IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF TEXAS
HOUSTON DIVISION

PAUL E. CALLINAN, and JORGE RIVERA, Individually and on Behalf of All Others Similarly Situated,	§	
Lead Plaintiffs,	§	
v.	§	CIVIL ACTION NO. H-19-0301
LEXICON PHARMACEUTICALS, INC., LONNEL COATS, JEFFREY L. WADE, and PABLO LAPUERTA,	§	
Defendants.	§	

MEMORANDUM OPINION AND ORDER

This action is brought against Lexicon Pharmaceuticals, Inc., ("Lexicon"), Lexicon's President, Chief Executive Officer ("CEO"), and a Director of Lexicon, Lonnel Coats ("Coats"), Lexicon's Chief Financial Officer ("CFO") and Vice President - Corporate and Administrative Affairs, Jeffrey L. Wade ("Wade"), and Lexicon's Executive Vice President and Chief Medical Officer Pablo Lapuerta ("Lapuerta"), for alleged violations of §§ 10(b) and 20(a) of the Securities Exchange Act of 1934 ("Exchange Act"), 15 U.S.C. §§ 78j(b) and 78t(a), and Rule 10b-5 promulgated thereunder, 17 C.F.R. § 240.10b-5, during a proposed class period beginning on March 11, 2016, and ending on July 29, 2019, both dates inclusive.[1]

[1]First Amended Class Action Complaint ("FACAC"), Docket Entry No. 27, pp. 2 and 14-15 ¶¶ 1 and 42-46. Page numbers for docket entries in the record refer to the pagination inserted at the top of the page by the court's electronic filing system.

Pending before the court are Defendants' Motion to Dismiss Plaintiffs' First Amended Complaint ("Defendant's Motion to Dismiss") (Docket Entry No. 33), and Plaintiffs' Memorandum of Law in Opposition to Defendants' Motion to Dismiss Plaintiffs' First Amended Complaint ("Plaintiffs' Opposition") (Docket Entry No. 35), in which plaintiffs request leave to amend "[i]f the Court grants any part of the [Defendants' Motion to Dismiss]."[2] Also before the court is Defendants' Reply Brief in Support of Their Motion to Dismiss Plaintiffs' First Amended Complaint ("Defendants' Reply") (Docket Entry No. 37). For the reasons stated below, the Defendants' Motion to Dismiss will be granted, and plaintiff's request for leave to amend will be denied.

I. **Procedural History and Alleged Facts**

Daniel Manopla initiated this action on January 28, 2019, by filing a Class Action Complaint (Docket Entry No. 1) asserting claims for violations of §10(b) and §20(a) of the Exchange Act and Rule 10b-5 promulgated thereunder. On April 1, 2019, Paul E. Callinan ("Callinan") and Jorge Rivera ("Rivers") filed their Motion for Appointment as Lead Plaintiffs and Approval of Counsel (Docket Entry No. 10). On May 31, 2019, the court signed an Order Approving Lead Plaintiffs and Approving Selection of Counsel (Docket Entry No. 23) appointing Callinan and Rivera as Lead

---

[2]Plaintiff's Opposition, Docket Entry No. 35, p. 31.

Plaintiffs, and approving their selection of Pomerantz LLP as Lead Counsel for the class and the Briscoe Law Firm, PLLC as Liaison Counsel for the class. On July 30, 2019, Lead Plaintiffs filed the FACAC (Docket Entry No. 27).

The FACAC alleges that Lexicon is a biopharmaceutical company focused "on the development and commercialization of 'breakthrough treatments,' i.e., drugs, 'for the treatment of human diseases.'"[3] The FACAC alleges that Lexicon is "a Delaware corporation with its principal executive offices located [in] . . . The Woodlands, Texas . . ., [and that its] common stock trades in an efficient market on the Nasdaq Global Select Market ("NASDAQ") under the ticker symbol 'LXRX.'"[4] The FACAC alleges that Coats has been the President, CEO, and a Director of Lexicon since July 2014,[5] Wade has been Lexicon's CFO and Vice President — Corporate and Administrative Affairs since February 2015, and that Lapuerta has been Lexicon's Executive Vice President and Chief Medical Officer since February 2015.[6]

The FACAC alleges that

> [a]t the start of the Class Period, on March 11, 2016, Lexicon filed its annual report on Form 10-K for the year 2015, which was signed by the Individual Defendants (the

---

[3]FACAC, Docket Entry No. 27, p. 2 ¶ 2. See also id. at 15 ¶ 49.

[4]Id. at 14 ¶ 43.

[5]Id. ¶ 44.

[6]Id. at 15 ¶ 46.

"2015 10-K"). That report disclosed, among other things, that Lexicon was "presently devoting most of our resources to the development of our two most advanced drug candidates." These drugs were "XERMELO," an oral treatment for carcinoid syndrome diarrhea, and sotagliflozin [trademarked "Zynquista"].

At the start of the class period, XERMELO, was in phase 3 clinical trials, and the Company was preparing to submit the medication for FDA approval. Sotagliflozin, Lexicon's other "most advanced drug candidate," had begun Phase III clinical trials as a treatment for T1d [Type 1 diabetes].[7]

The FACAC alleges that in 2015 Lexicon

> entered into a collaboration and license agreement for sotagliflozin with Sanofi. Under the Sanofi Agreement, Lexicon granted Sanofi an exclusive, worldwide, royalty-bearing right and license to develop, manufacture and commercialize sotagliflozin. Lexicon, however, was responsible for all clinical development activities related to T1d and retained an exclusive option to co-promote and collaborate with Sanofi, in the commercialization of sotagliflozin for the treatment of T1d in the United States. Sanofi was responsible for all clinical development and commercialization of sotagliflozin for the treatment of T2d [Type 2 diabetes] worldwide and was solely responsible for the commercialization of sotagliflozin for the treatment of T1d outside the United States. Sanofi could terminate the agreement if a regulatory body found the risks associated with sotagliflozin so severe that Lexicon and Sanofi had to stop developing the drug, or if the drug failed to achieve certain results at the endpoints of phase 3 clinical trials for T1d or T2d. Under the Sanofi Agreement, Lexicon received a $300 million upfront payment . . . and was eligible to receive up to $430 million upon the achievement of specified development and regulatory milestones and up to $990 million upon the achievement of specified sales milestones.[8]

---

[7]Id. at 16 ¶¶ 50-51. See also id. at 2 ¶ 3 (stating that sotagliflozin is trademarked "Zynquista").

[8]Id. ¶ 52. See also Collaboration and License Agreement between Lexicon Pharmaceuticals, Inc. and Sanofi Dated as of November 5, 2015, Exhibit 2 to Defendants' Motion to Dismiss, (continued...)

The FACAC alleges that in 2015 Lexicon had debt of $1.1 billion and revenues of $130 million,[9] which was almost entirely attributable to the initial $300 million payment received pursuant to the Sanofi Agreement.[10] The FACAC alleges that Lexicon reported a loss of $4.7 million in 2015, and greater losses in each of three following years, i.e., over $131 million loss in 2016, over $122 million loss in 2017, and over $120 million loss in 2018.[11] The FACAC alleges that Lexicon's cash reserves fell by 70% during the Class Period from approximately $521 million in reported for 2015 to $133 million as of March 31, 2019.[12] The FACAC alleges that "[b]oth Defendants and investors knew that Lexicon would not be able to become profitable – or perhaps even survive – unless the FDA approved Lexicon's products,"[13] and that "[d]efendants also knew that obtaining FDA approval for sotagliflozin would transform the T1d industry," because it "would be the first oral antidiabetic drug approved in the U.S. for use by adults with [T1d], in combination with insulin."[14]

---

[8](...continued)
Docket Entry No. 34-2.

[9]FACAC, Docket Entry No. 27, p. 17 ¶ 53.

[10]Id. ¶ 55.

[11]Id.

[12]Id. at 17-18 ¶ 56.

[13]Id. at 18 ¶ 57.

[14]Id. at 19-20 ¶ 61.

The FACAC alleges that "T1d is an autoimmune disease that renders T1d sufferers unable to produce insulin,"[15] "[t]here is no cure for T1d," and "sufferers treat their T1d by monitoring their glucose levels throughout the day and injecting insulin multiple times per day using insulin pens, syringes or an insulin pump."[16]

> People who suffer from T2d [Type 2 diabetes] . . . produce insulin, but have developed a condition where their bodies do not use that insulin properly. There is no cure for T2d. Although some sufferers can manage T2d via diet and exercise, T2d usually gets worse over time and they eventually may be prescribed oral medications and insulin.[17]

The FACAC alleges that

> T1d and T2d can be diagnosed using a variety of tests. One common blood test used to diagnose T1d and T2d, as well as to monitor both conditions, is a test of a patient's "HbA1c levels." . . . HbA1c reflects the average glucose level in a patient's bloodstream over the prior two to three months and is determined by measuring what percentage of the patient's hemoglobin i[s] covered with glucose, or "glycated." The higher a patient's HbA1c test percentage, the higher their risk of diabetes complications. Whether a drug is shown to reduce HbA1c levels is a key factor in whether the drug will be approved to treat diabetes.
>
> A person who does not have diabetes, will have a "normal" HbA1c level below 5.7%. A person with an HbA1c level between 5.7% and 6.4% is said to have "prediabetes" and is at risk of developing diabetes in the future. A person with an HbA1c level of 6.5% or higher on two separate occasions has diabetes, and an HbA1c level over 8% indicates that the person's diabetes is not well-controlled and the person is at risk of diabetes

---

[15] Id. at 20 ¶ 62.

[16] Id. ¶ 64.

[17] Id. at 21 ¶ 65.

> complications. Over half of T1d sufferers have an HbA1c level **over 8%.** Most diabetes sufferers, including T1d sufferers, aim for an HbA1c level of 7% or lower.
>
> T1d and T2d sufferers are at risk of a variety of complications stemming from their bodies' inability to move glucose from their blood to their cells. One of these complications is "hyperglycemia" or "high blood glucose," which occurs when there is too much glucose in the blood. If left untreated, hyperglycemia can result in DKA. DKA is a serious, life-threatening condition that develops when diabetes sufferers do not produce enough insulin and their bodies are unable to use glucose in their blood for fuel. Without glucose, diabetes sufferers begin to break down fats to use for energy, which results in a build-up of acids in the bloodstream called "ketones." The build-up of ketones causes DKA and, if left untreated, DKA can lead to diabetic coma or death. People with T1d are much more likely to experience DKA than people with T2d.[18]

The FACAC alleges that

> sotagliflozin was developed by the Company's own chemists as a medication that inhibits two sodium-glucose cotransporters: sodium-glucose cotransporter type 1, or "SGLT-1," which is a protein that enables the body's [] gastrointestinal tract to absorb glucose, and sodium-glucose cotransporter type 2, or "SGLT-2," a protein that performs the same function in the kidneys. When the body's SGLT-1 and SGLT-2 proteins are operating normally, they enable the body to preserve glucose for use as energy that would otherwise be passed out of the body through urination. In theory, sotagliflozin would prevent the glucose filtered out by the body's gastrointestinal tract and kidneys from being reabsorbed into the body, which would pass out of the body via urination and lower a T1d patient's blood glucose.[19]

The FACAC alleges that "[i]n March [of] 2013 the FDA approved Canagliflozin, a sodium-glucose cotransporter inhibitor that only

---

[18]<u>Id.</u> at 21-22 ¶¶ 66-68.

[19]<u>Id.</u> at 22-23 ¶ 69.

worked to inhibit SGLT-2, for treatment of T2d,"[20] that subsequently the FDA grew so concerned by the incidences of DKA in diabetes sufferers being treated with the approved SGLT-2 inhibitor that on May 15, 2015, it issued a public "Drug Safety Communication" warning of the risk of DKA to users of SGLT-2 inhibitors,[21] and that on December 15, 2015, it announced that all SGLT-2 inhibitors would have to have labels warning about DKA.[22]

The FACAC alleges that in 2015

> Lexicon had arranged for three phase 3 trials to assess the safety and efficacy of sotagliflozin in approximately 3,000 adults with inadequately controlled T1d. Lexicon named the trials "inTandem 1," inTandem 2," and "inTandem 3" (the "Phase 3 Trials"). InTandem 1 and inTandem 2 tested 200 mg and 400 mg doses of sotagliflozin, while inTandem 3 only tested 400 mg doses of the drug.
>
> The inTandem 1 and inTandem 2 trials began with a 24-week double-blind treatment period, which was followed by a 28-week extension period. In addition, both trials enrolled T1d patients who at the time they were screened had HbA1c levels between 7% and 11%, although at the time the trials began, there was no limit on their HbA1c levels. The trials enrolled patients with a history of DKA, as long as the patients had not experienced DKA in the four weeks prior to screening and had no more than 2 episodes of DKA in the prior 6 months.[23]

The FACAC alleges that "[d]efendants knew that prior phase 2 trials suggested that sotagliflozin was associated with the occurrence of

[20] Id. at 23 ¶ 70.

[21] Id.

[22] Id. ¶ 71.

[23] Id. at 24 ¶¶ 72-73.

DKA,"[24] and that "[b]ased on the FDA's . . . concern about the incidence of DKA in SGLT-2 inhibitors, [d]efendants knew that significant incidences of DKA could cause the FDA to not approve the drug because DKA was so substantial a health risk for diabetes sufferers."[25] The FACAC alleges that

> [d]efendants decided to design the Phase 3 Trials so that the results would over-emphasize sotagliflozin's benefits and downplay the risks of DKA. For example, to put the maximum emphasis on sotagliflozin's benefits, [d]efendants set the "primary endpoint" of the inTandem1 and inTandem2 trials as the "change from baseline HbA1c by week 24 of the trial." In other words, as long as HbA1c levels had declined by a certain amount by the end of the trials, the trials had obtained positive results <u>regardless of the incidence of DKA.</u>
>
> Defendants then designed a "secondary endpoint" for the inTandem1 and inTandem2 trials as a "composite endpoint" that measured the "proportion of patients who achieved an A1c of less than 7% without an episode of severe hypoglycemia or DKA." The composite endpoint thus focused on <u>the number of patients that had HbA1c under 7%</u> and did not discuss the incidence of DKA other than in the context of how many <u>more</u> patients were benefitting from the drug than had experienced the catastrophic, life-threatening condition. Defendants were so enamored with this composite endpoint that they used it as the <u>primary endpoint</u> for the inTandem3 Phase 3 Trial.
>
> Defendant Coats assured analysts and investors that Lexicon had tailored the Phase 3 Trials to address the FDA's concerns about the safety and efficacy of sotagliflozin, telling attendees on a March 4, 2015 call with investors . . . that, "[t]he key is to stay focused on type 1 diabetes, which is where we are and be able to answer all the other questions that [the FDA] have for us, in terms of being able to show the balance of safety and efficacy, as these studies roll forward, **<u>and we have</u>**

[24]<u>Id.</u> at 24 ¶ 74.

[25]<u>Id.</u>

structured these studies to achieve that." Defendants did not disclose, however, that this meant that the studies were designed to emphasize the benefits of sotagliflozin and hide the occurrence of DKA.

The FDA told [d]efendants that the "composite endpoint" it planned to use in the Phase 3 Trials was likely to create misleading results. The FDA likely told [d]efendants this in 2015, prior to the start of the Phase 3 Trials, or, at the very latest, by March 2018. Indeed, in a presentation to the FDA's Endocrinologic and Metabolic Drugs Advisory Committee on January 17, 2019, an FDA representative said that "[d]uring presubmission meetings with the sponsor [i.e., prior to March 26, 2018], the FDA expressed concern about the utility of the composite endpoint and whether it would be adequate to characterize the overall benefit-risk" of sotagliflozin. Jan. 17, 2019, Advisory Committee Meeting Transcript ("Comm. Tr.") 118:15-19. In other words, [d]efendants had actual knowledge that the FDA was concerned with the composite endpoint used by Lexicon in its Phase 3 Trials, which significantly affected the likelihood that the FDA would approve the drug, but never disclosed that fact to investors.[26]

The FACAC alleges that

> [d]efendants publicly disclosed top-line primary efficacy endpoint data for the inTandem1 trial in September 2016 and additional data in May 2017; top-line primary efficacy endpoint data for the inTandem2 trial in December 2016 and additional data in August 2017; top-line data for the inTandem3 trial in June 2017; and pooled data for the inTandem1 and inTandem2 clinical trials in September 2017. These disclosures consisted of, among other things, changes in patients' HbA1c levels, weight loss, incidences of hypoglycemia and incidences of DKA. Although Defendants publicly disclosed the Phase 3 Trial results in September 2016, December 2016, May 2017, August 2017 and September 2017, they obtained, and thus had actual knowledge of, the Phase 3 Trial results in advance of these public disclosures.

[26] Id. at 24-26 ¶¶ 75-78.

> After receiving the data, rather than disclose the truth about sotagliflozin to investors, [d]efendants began a campaign designed to emphasize its modest benefits while concealing its risks. . .[27]

The FACAC alleges that

> [i]ncidences of DKA exploded during the Phase 3 Trials. Indeed, materials created by the FDA summarizing the results of the Phase 3 Trials revealed that there had been an **eightfold increase of DKA for sotagliflozin users over placebo.**
>
> Not only did the Phase 3 Trials reflect a dramatic increase in DKA for patients taking sotagliflozin, but the inTandem1 and inTandem2 trials showed that virtually all of the incidences of DKA qualified as "serious," as defined by regulatory guidance, and **over 68% of the instances were assessed by trial investigators to be severe.**
>
> The incidence of DKA also **increased** over the course of the 52-week trials and continued to increase in spite of Lexicon's efforts to identify and manage those incidences. For example, Lexicon instructed investigators conducting the trials to closely monitor subjects for potential indicators of DKA, and gave test subjects expensive ketone testing strips and BHB monitors so that patients could check for signs of DKA, but none of these measures were effective in limiting the incidence of DKA. But the DKA that affected patients in the Phase 3 Trials was **unique** in that the symptoms that usually suggested the onset of DKA, like increased thirst or urination, **were not reliable to detect DKA in patients taking sotagliflozin during the Phase 3 Trials.** This meant that patients had fewer early signs and symptoms and had to rely on ketone tests to see if a DKA episode was imminent. Patients were also at a risk of DKA for longer periods while on sotagliflozin because the medication had a long "half-life," meaning it remained in the body for long periods of time, expanding the timeframe when DKA could develop. The incidence of DKA in the Phase 3 Trials was so evenly dispersed that Lexicon could not identify classes of patients that were at greater risk of

---

[27] Id. at 29 ¶¶ 87-88.

DKA on sotagliflozin. Defendants never disclosed any of these issues concerning DKA to investors.

To make matters worse, the effect that sotagliflozin was having on patients' HbA1c levels was not meaningful. The Phase 3 Trials only showed an average reduction of HbA1c for patients taking sotagliflozin of 0.3% to 0.4%, and an average weight loss of 2 to 3 kilograms per patient. Since over half of people with T1d have HbA1c levels over 8%, a decline of **0.3% to 0.4%** would not have a substantial effect on T1d sufferers, who generally hope to achieve HbA1c levels of 7%. In addition, by reporting the average reduction in HbA1c, the Phase 3 Trials were potentially concealing the existence of a large number of insignificant declines in HbA1c, e.g., from 7.0% to 6.9%, with a small number of large decreases in an HbA1c in a patient with a high HbA1c level, e.g., from 8.5% to 7.2%. Since the HbA1c declines reported in the Phase 3 Trials were not meaningful, they were not likely to outweigh the extraordinary risk to patients posed by the increase in DKA.

Similarly, the average weight loss experienced by a patient on sotagliflozin was less than 5% per patient, which also was not statistically meaningful. Finally, while patients in inTandem 1 and inTandem2 trials did see a decrease in hypoglycemia, a different life-threatening condition for diabetics that is caused by low blood sugar, incidence of hypoglycemia had increased over placebo in patients in the inTandem3 trial.

In short, the sotagliflozin Phase 3 Trials showed a spike in incidences of DKA that were severe, difficult to identify and respond to, and resistant to [d]efendants' attempts to manage them. In addition, the spike in DKA had occurred in a tightly regulated clinical trial setting, which strongly suggested that the rate in DKA was actually **understated** compared to what would occur when the drug was marketed commercially. Finally, the relatively low benefits that some patients experienced were unlikely to be seen as outweighing the risks presented by the drug.

In sum, the increases in DKA, over two-thirds of which were assessed to be severe; the modest reductions in HbA1c and weight; and the inconclusive trend of hypoglycemia in the Phase 3 Trials provided strong evidence that the FDA would not approve sotagliflozin.

Defendants, however, did not disclose this information to investors. Instead, [d]efendants used the Phase 3 Trials, which they had designed to conceal the risks posed by DKA, in a campaign to obtain FDA approval by misleadingly touting the purported benefits of sotagliflozin and concealing the risks of DKA.[28]

The FACAC alleges that

[d]efendants had actual knowledge that the statements they were making about the performance of sotagliflozin in the Phase 3 Trials were misleading because Lexicon was responsible for the clinical development of sotagliflozin for T1d under the Sanofi Agreement, had met with FDA officials and had received data directly from the investigators conducting the trials, the development of sotagliflozin was essential for [] Lexicon's survival, and [d]efendants had designed the Phase 3 Trials to conceal the increased risk of DKA.

In addition, confidential witnesses who worked for [d]efendants corroborated [d]efendants' knowledge of the problems with sotagliflozin in the Phase 3 Trials. . .[29]

The FACAC alleges that

[o]n March 26, 2018, Lexicon announced that Sanofi had submitted a new drug application ("NDA") to the FDA for sotagliflozin. The NDA sought approval for sotagliflozin "as an adjunct to insulin in adults with [T1d], for two proposed doses: 200 mg and 400 mg, both given twice daily. . . By filing the NDA, Sanofi was the "sponsor" of sotagliflozin. On May 22, 2018, Lexicon issued a press release announcing that the FDA had accepted Sanofi's NDA.[30]

---

[28]Id. at 26-28 ¶¶ 79-85.

[29]Id. at 33 ¶¶ 96-97.

[30]Id. at 34 ¶ 100.

In November of 2018 the FDA announced that an Advisory Committee, a group of independent experts, would hold a public meeting on January 17, 2019, to discuss the NDA for sotagliflozin.[31]

The FACAC alleges that before the Advisory Committee Meeting both Lexicon (through Sanofi, as the "sponsor" of sotagliflozin), and the FDA submitted briefing materials to the Advisory Committee. Sanofi's briefing materials characterized the Phase 3 Trials as showing that sotagliflozin "added to standard-of-care insulin and glucose management, consistently and significantly reduced A1c compared to placebo without increasing the risk of severe hypoglycemia," and that HbA1c reductions "occurred in conjunction with improvements in measures of day-to-day blood glucose variability [i.e., Glycemic Variability], treatment satisfaction and diabetes distress," and "without weight gain caused by intensification of insulin treatment." Sanofi's briefing materials acknowledged that "sotagliflozin increases the risk of DKA," but argued that risk could be "managed with appropriate measures." Sanofi's briefing materials also proposed a risk mitigation program that consisted of advising physicians to carefully screen patients at higher risk of DKA, offering literature asking patients to lookout for DKA symptoms, to check their ketone levels, and to contact a healthcare provider if their ketone levels were positive.[32]

---

[31]Id. ¶ 101.

[32]Id. at 35-36 ¶¶ 102-04 (quoting Sanofi Briefing Document,
(continued...)

The FDA's briefing materials emphasized the risk of DKA to patients taking sotagliflozin stating, "sotagliflozin therapy clearly increases that risk, and the risk may be unpredictable,"[33] stating concerns about the clinical significance of the composite endpoint used by Lexicon, and "suggested that the endpoint was not 'a clinically meaningful way to frame both the benefits and the risks of sotagliflozin.'"[34] Acknowledging that while the time-in-range and glycemic variability results are "valued by patients and may relate to at least short-term improvements in quality of life and treatment satisfaction," the FDA briefing materials stated that those measures **"do not have an established relationship with long-term macrovascular and microvascular complications** and **have not been validated for use in regulatory decision making for antidiabetic drugs.**"[35]

The FACAC alleges that the FDA "noted that '[d]uring presubmission meetings with the sponsor, the FDA expressed concern

(...continued)
pp. 16, 19, and 22, Exhibit 2 to Defendants' Motion to Dismiss, Docket Entry No. 34-2, pp. 18, 21, and 24).

[33] Id. at 36 ¶ 105 (quoting FDA Briefing Document, p. 11, Exhibit 6 to Defendants' Motion to Dismiss, Docket Entry No. 34-6, p. 12).

[34] Id. (quoting FDA Briefing Document, p. 11, Exhibit 6 to Defendants' Motion to Dismiss, Docket Entry No. 34-6, p. 12).

[35] Id. at 36-37 ¶ 107 (quoting FDA Briefing Document, p. 10, Exhibit 6 to Defendants' Motion to Dismiss, Docket Entry No. 34-6, p. 11).

about the utility of the composite endpoint and whether it would be adequate to characterize the overall benefit-risk.'"[36]

The FACAC alleges that the FDA

> harshly criticized [d]efendants' use of the composite endpoint, telling the Advisory Committee that [r]eductions in HbA1c, severe hypoglycemia, and DKA, are of different clinical importance, but **<u>when they were lumped together, the increased risk in a more severe but less frequent component, DKA, would be hidden</u>** . . . [s]ponsor defined net benefit masked increased risk in DKA in sotagliflozin groups.[37]

In addition the FDA said that "[t]he rate of DKA continued to increase for the sotagliflozin group throughout the trial while the rate for placebo remains flat."[38] The FDA concluded **<u>"we think the sponsor-defined net benefit endpoint masked the increased risk of DKA in the sotagliflozin groups and does not actually assess the net benefit of the product or help inform the overall benefit-risk assessment.</u>**"[39] The FACAC alleges that the sponsor admitted attempts to address the increase of DKA during the trial had no effect.[40]

---

[36] <u>Id.</u> at 39 ¶ 116 (quoting Advisory Committee Meeting Transcript, p. 118:15-19, Exhibit 8 to Defendants' Motion to Dismiss, Docket Entry No. 34-15, p. 119).

[37] <u>Id.</u> at 40 ¶ 117 (citing Advisory Committee Meeting Transcript, p. 126:2-7, Exhibit 8 to Defendants' Motion to Dismiss, Docket Entry No. 34-15, p. 127).

[38] <u>Id.</u> (citing Advisory Committee Meeting Transcript, p. 138:13-15, Exhibit 8 to Defendants' Motion to Dismiss, Docket Entry No. 34-15, p. 139).

[39] <u>Id.</u> (citing Advisory Committee Meeting Transcript, p. 127:14-18, Exhibit 8 to Defendants' Motion to Dismiss, Docket Entry No. 34-15, p. 129).

[40] <u>Id.</u> at 41 ¶ 121 (citing Advisory Committee Meeting (continued...)

At the end of the meeting the Advisory Committee voted eight to eight on the question of whether the overall benefits of sotagliflozin outweighed the risks to support approval, and did not recommend sotagliflozin for approval.[41] The FACAC alleges that

> [e]ach of the Advisory Committee members were given the opportunity after voting to explain the basis for their vote. All eight committee members who voted "no" pointed to the dramatic increase in DKA during the Phase 3 Trials, which [d]efendants worked so hard to conceal, as outweighing the benefits of the drug. In addition the "no" voters said that the only benefit Lexicon and Sanofi had demonstrated from sotagliflozin was a "modest reduction[] in HbA1c" and that there was no evidence that the risk mitigation strategy of patient screening and ketone monitoring would have any effect on the risk of DKA. The "no" voters also repeatedly emphasized that the closely controlled setting of the Phase 3 Trials likely understated the risk of DKA. One committee member summed it up by saying, "we didn't get to hear from people who had DKA, and their life might have changed from that potentially life-threatening outcome. **Its increased eightfold, which I couldn't get over.**"[42]

The FACAC alleges that while trading in Lexicon's stock was suspended on Thursday, January 17, 2019, the day of the Committee Meeting, that when trading resumed on Friday, January 18, 2019, Lexicon's stock price declined roughly 23% to close at $5.96 per share, and then fell to $4.46 per share on January 25, 2019, as the

---

[40](...continued) Transcript, p. 288:22-289:4, 290:5-9, Exhibit 8 to Defendants' Motion to Dismiss, Docket Entry No. 34-15, pp. 289-91).

[41]Id. at 43 ¶ 126.

[42]Id. ¶ 127 (citing Advisory Committee Meeting Transcript, p. 373:12-19, Exhibit 8 to Defendants' Motion to Dismiss, Docket Entry No. 34-15, p. 374).

market digested the implications of the Advisory Committee's deadlock.[43] The FACAC alleges that

> [t]hese declines were attributable to the disclosure of the Advisory Committee's deadlock on sotagliflozin, which revealed that [d]efendants had been making false and misleading statements and/or omissions concerning the risk to patients of DKA, the drug's effectiveness, the FDA's concerns regarding the "composite endpoint" in the Phase 3 Trials and [d]efendants' touting of . . . sotagliflozin's performance with regards to measures that had not been validated by the FDA for use in regulatory decision making.[44]

The FACAC alleges that on March 22, 2019, Lexicon announced that the FDA had issued a "Complete Response Letter" ("CRL") informing it that the FDA would not approve sotagliflozin. Defendants held a call with analysts later that day but refused to identify the reasons why the FDA rejected sotagliflozin.[45] On news of the FDA's CRL, Lexicon's stock price fell 21.9% to close at $6.20 per share on March 22, 2019, and fell to $5.26 per share on March 28, 2019, as the market digested the CRL's implications.[46]

The FACAC alleges that

> [o]n July 26, 2019, Sanofi disclosed that the top-line results for two (out of a total of 10) phase 3 trials it was conducting on the efficacy of sotagliflozin as a treatment for T2d failed to achieve "statistically significant reductions" in HbA1c, and that Sanofi was terminating the Sanofi Agreement. Sanofi's termination

---

[43]Id. at 43-44 ¶ 128.

[44]Id.

[45]Id. at 44 ¶ 130.

[46]Id. at 45 ¶ 132.

> of the Sanofi Agreement was clearly the result of the Advisory Committee's deadlocked vote, which led to the FDA's decision to reject sotagliflozin. This was a materialization of the risk stemming from [d]efendants' false and misleading statements and/or omissions concerning the risk to patients of DKA, the drug's effectiveness, the FDA's concerns regarding the "composite endpoint" in the Phase 3 Trials and [d]efendants' touting of . . . sotagliflozin's performance with regards to measures that had not been validated by the FDA for use in regulatory decision making, which had already led to the Advisory Committee's deadlocked vote at the Committee Meeting and the FDA's decision not to approve sotagliflozin as a T1d treatment.[47]

The FACAC alleges that following news that the Sanofi Agreement was being terminated, Lexicon's stock price fell **$4.00 per share, or 70.3%,** to close at $1.69 per share on July 29, 2019."[48]

II. Defendants' Motion to Dismiss

Defendants argue that the FACAC should be dismissed pursuant to Federal Rule of Civil Procedure 12(b)(6) because plaintiffs have failed to satisfy the pleading requirements for stating either a primary claim under § 10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder or a secondary claim for control person liability under § 20(a) of the Exchange Act.[49] Defendants argue that plaintiffs have failed to allege facts capable of establishing

---

[47] Id. at 46 ¶ 135.

[48] Id. ¶ 136.

[49] Defendants' Motion to Dismiss, Docket Entry No. 33, pp. 6, 30.

(1) that they made an actionable misstatement or omission; (2) that any actionable misstatement or omission was made with scienter; or (3) caused the loss for which plaintiffs seek relief.[50] Defendants argue that the control-person claims under § 20(a) asserted against the Individual Defendants fail because plaintiffs have failed to state a claim for securities fraud under §10(b) or Rule 10b-5.[51]

A. Standards of Review

1. Federal Rule of Civil Procedure 12(b)(6)

Defendants' motion to dismiss is governed by Federal Rule of Civil Procedure 12(b)(6). A Rule 12(b)(6) motion tests the formal sufficiency of the pleadings and is "appropriate when a defendant attacks the complaint because it fails to state a legally cognizable claim." Ramming v. United States, 281 F.3d 158, 161 (5th Cir. 2001), cert. denied sub nom. Cloud v. United States, 122 S. Ct. 2665 (2002). The court must accept the factual allegations of the complaint as true, view them in a light most favorable to the plaintiff, and draw all reasonable inferences in the plaintiff's favor. Id. To defeat defendants' motion to dismiss Lead Plaintiff must plead "enough facts to state a claim to relief that is plausible on its face." Bell Atlantic Corp. v. Twombly,

---

[50] Id. See also id. at 18-27 (misrepresentations); 27-29 (scienter); 29-30 (loss causation). See also Defendants' Reply, Docket Entry No. 37, pp. 7-10 (failure to plead scienter).

[51] Id. at 30.

127 S. Ct. 1955, 1974 (2007). "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." Ashcroft v. Iqbal, 129 S. Ct. 1937, 1949 (2009) (citing Twombly, 127 S. Ct. at 1965). "Where a complaint pleads facts that are 'merely consistent with' a defendant's liability, it 'stops short of the line between possibility and plausibility of entitlement to relief.'" Id.

When considering a motion to dismiss courts generally are limited to the complaint and its proper attachments. Dorsey v. Portfolio Equities, Inc., 540 F.3d 333, 338 (5th Cir. 2008). Courts may, however, also "rely on 'documents incorporated into the complaint by reference, and matters of which a court may take judicial notice.'" Id. (quoting Tellabs, Inc. v. Makor Issues & Rights, Ltd., 127 S. Ct. 2499, 2509 (2007)). See also Truk International Fund LP v. Wehlmann, 737 F. Supp. 2d 611, 616 (N.D. Tex. 2009), aff'd, 389 F. App'x 354 (5th Cir. 2010) (courts may consider "the full text of documents partially quoted in the complaint"). In securities cases courts may take judicial notice of the contents of public disclosure documents that are required by law to be filed with the SEC and are actually filed with the SEC, with the caveat that these documents may be considered only for the purpose of determining the statements they contain; not for proving the truth of their contents. Lovelace v. Software Spectrum Inc., 78 F.3d 1015, 1018 & n.1 (5th Cir. 1996).

2. Federal Securities Law

Section 10(b) of the Exchange Act makes it unlawful

> [t]o use or employ, in connection with the purchase or sale of any security . . . any manipulative or deceptive device or contrivance in contravention of such rules and regulations as the [SEC] may prescribe as necessary or appropriate in the public interest or for the protection of investors.

15 U.S.C. § 78j(b). Rule 10b-5 makes it

> unlawful for any person, directly or indirectly, by the use of any means or instrumentality of interstate commerce, or of the mails or of any facility of any national securities exchange,
>
> (a) To employ any device, scheme, or artifice to defraud,
>
> (b) To make any untrue statement of a material fact or to omit to state a material fact necessary in order to make the statements made, in the light of the circumstances under which they were made, not misleading, or
>
> (c) To engage in any act, practice, or course of business which operates or would operate as a fraud or deceit upon any person, in connection with the purchase or sale of any security.

17 C.F.R. § 240.10b-5. To recover damages for violations of § 10(b) and Rule 10b-5, plaintiffs must prove

> (1) a material misrepresentation or omission by the defendant; (2) scienter; (3) a connection between the misrepresentation or omission and the purchase or sale of a security; (4) reliance upon the misrepresentation or omission; (5) economic loss; and (6) loss causation.

Halliburton Co. v. Erica P. John Fund, Inc., 134 S. Ct. 2398, 2407 (2014) (quoting Amgen Inc. v. Connecticut Retirement Plans and Trust Funds, 133 S. Ct. 1184, 1192 (2013) (quoting Matrixx Initiatives, Inc. v. Siracusano, 131 S. Ct. 1309, 1317-18 (2011)).

A fact is material if the reasonable investor would have found the fact significant in making the decision to invest. Basic Inc. v. Levinson, 108 S. Ct. 978, 986 (1988). Such claims are subject to pleading requirements of both Federal Rule of Civil Procedure 9(b) and the Private Securities Litigation Reform Act ("PSLRA"). Lormand v. US Unwired, Inc., 565 F.3d 228, 239 (5th Cir. 2009).

(a) Federal Rule of Civil Procedure 9(b)

Rule 9(b) requires that "[i]n alleging fraud or mistake, a party must state with particularity the circumstances constituting fraud or mistake. Malice, intent, knowledge, and other conditions of a person's mind may be alleged generally." Fed.R.Civ.P. 9(b). Pleading fraud with particularity in this circuit requires "the particulars of 'time, place, and contents of the false representations, as well as the identity of the person making the misrepresentation and what [that person] obtained thereby.'" Tuchman v. DSC Communications Corp., 14 F.3d 1061, 1068 (5th Cir. 1994) (quoting Tel-Phonic Services, Inc. v. TBS International, Inc., 975 F.2d 1134, 1139 (5th Cir. 1992)). See also Carroll v. Fort James Corp., 470 F.3d 1171, 1174 (5th Cir. 2006) (quoting United States ex rel. Riley v. St. Luke's Episcopal Hospital, 355 F.3d 370, 381 (5th Cir. 2004) ("In cases concerning fraudulent misrepresentation and omission of facts, Rule 9(b) typically requires the claimant to plead the type of facts omitted, the place

in which the omissions should have appeared, and the way in which the omitted facts made the representations misleading.")). "A dismissal for failure to plead fraud with particularity as required by Rule 9(b) is a dismissal on the pleadings for failure to state a claim." Southland Securities Corp. v. INSpire Insurance Solutions, Inc., 365 F.3d 353, 361 (5th Cir. 2004) (citing Shushany v. Allwaste, Inc., 992 F.2d 517, 520 (5th Cir. 1993)).

(b) Private Securities Litigation Reform Act

In 1995 Congress amended the Exchange Act by passing the PSLRA, 15 U.S.C. § 78u-4(b)(1), which, in relevant part, states:

> (1) Misleading statements and omissions
>
> In any private action arising under this chapter in which the plaintiff alleges that the defendant--
>
> > (A) made an untrue statement of a material fact; or
> >
> > (B) omitted to state a material fact necessary in order to make the statements made, in the light of the circumstances in which they were made, not misleading;
>
> the complaint shall specify each statement alleged to have been misleading, the reason or reasons why the statement is misleading, and, if an allegation regarding the statement or omission is made on information and belief, the complaint shall state with particularity all facts on which that belief is formed.
>
> (2) Required state of mind
>
> > (A) In general
> >
> > Except as provided in subparagraph (B), in any private action arising under this chapter in which the plaintiff may recover money damages only on

> proof that the defendant acted with a particular state of mind, the complaint shall, with respect to each act or omission alleged to violate this chapter, state with particularity facts giving rise to a strong inference that the defendant acted with the required state of mind.
>
> . . .
>
> (3) Motion to dismiss; stay or discovery
>
> (A) Dismissal for failure to meet pleading requirements
>
> In any private action arising under this chapter, the court shall, on the motion of any defendant, dismiss the complaint if the requirements of paragraphs (1) and (2) are not met.

15 U.S.C. § 78u-4(b). The PSLRA's heightened pleading standard is targeted at preventing abusive securities litigation. See Tellabs, 127 S. Ct. at 2504 ("Private securities fraud actions . . . if not adequately contained, can be employed abusively to impose substantial costs on companies and individuals whose conduct conforms to the law.").

In ABC Arbitrage Plaintiffs Group v. Tchuruk, 291 F.3d 336, 350 (5th Cir. 2002), the Fifth Circuit combined the Rule 9(b) and the PSLRA pleading requirements into one succinct directive:

> [A] plaintiff pleading a false or misleading statement or omission as the basis for a section 10(b) and Rule 10b-5 securities fraud claim must, to avoid dismissal pursuant to Rule 9(b) and [the PSLRA]:
>
> (1) specify each statement alleged to have been misleading, i.e., contended to be fraudulent;
>
> (2) identify the speaker;
>
> (3) state when and where the statement was made;

> (4) plead with particularity the contents of the false representations;
>
> (5) plead with particularity what the person making the misrepresentation obtained thereby; and
>
> (6) explain the reason or reasons why the statement is misleading, i.e., why the statement is fraudulent.
>
> This is the "who, what, when, where, and how" required under Rule 9(b) in our securities fraud jurisprudence and under the PSLRA. Additionally, under [the PSLRA], for allegations made on information and belief, the plaintiff must:
>
> (7) state with particularity all facts on which that belief is formed, i.e., set forth a factual basis for such belief.

In Indiana Electrical Workers' Pension Trust Fund IBEW v. Shaw Group, Inc., 537 F.3d 527, 533 (5th Cir. 2008), the Fifth Circuit held that the PSLRA enhanced the particularity requirements for pleading private claims of securities fraud by requiring plaintiffs (1) to "specify each statement alleged to have been misleading, [and] the reason or reasons why the statement is misleading. . .;" and (2) "for each act or omission alleged to be false or misleading . . . state with particularity facts giving rise to a strong inference that the defendant acted with the required state of mind." Quoting Tellabs, 127 S. Ct. at 2509-10, the Fifth Circuit acknowledged that "a court must take into account plausible inferences opposing as well as supporting a strong inference of scienter," and that "[t]he inference of scienter must ultimately be 'cogent and compelling,' not merely 'reasonable' or 'permissible.'" Indiana Electrical, 537 F.3d at 533. In Lormand, 565 F.3d at 257-

58, however, the Fifth Circuit held that the PSLRA did not heighten the pleading requirements for loss causation, which remain subject to Federal Rule of Civil Procedure 8(a)(2)'s plausibility standard.

The PSLRA contains a safe harbor provision that protects defendants from liability for certain forward-looking statements that later prove false. 15 U.S.C. § 78u-5(c)(1)(A)(i, ii). "To avoid the safe harbor, plaintiffs must plead facts demonstrating that the statement was made with actual knowledge of its falsity." Southland, 365 F.3d at 371.

B. Analysis

1. Claims for Violation of § 10(b) and Rule 10b-5

(a) The Misrepresentations Alleged Are Not Actionable

The FACAC alleges that defendants misrepresented the results of the Phase 3 Trials for sotagliflozin on 19 different occasions: four Form 10-Ks and the related SOX Certifications filed with the SEC in March of 2016, 2017, 2018, and 2019; nine Press Releases issued on September 9, 2016, December 21, 2016, May 11, 2017, June 9, 2017, August 15, 2017, September 8 and 13, 2017, and June 23 and 24, 2018; three Earnings Calls held on August 4, 2016, September 9, 2016, and November 8, 2017; and three presentations at conferences held on January 11, 2017, September 5, 2018, and January 9, 2019.[52] The FACAC alleges that

[52] FACAC, Docket Entry No. 27, pp. 46-68 ¶¶ 137-198.

> [d]efendants made their materially false and misleading statements and/or omissions about sotagliflozin throughout the Class Period in SEC filings, press releases, presentations, and conference calls with investors and analysts. Their statements uniformly (i) concealed the stunning increases in DKA associated with sotagliflozin over placebo; (ii) failed to disclose that the FDA had warned against using the "composite endpoint" in the Phase 3 Trials, (iii) misrepresented the benefits of sotagliflozin; (iv) failed to disclose that the Time-in-Range and Glycemic Variability measures Lexicon touted were not validated for use in regulatory decision making for antidiabetic drugs; (v) failed to disclose that Lexicon did not have a meaningful risk management plan for DKA, which was essential to the approval of sotagliflozin.[53]

Asserting that "[t]he gravamen of the FAC[AC] is that investors were blind sided by [the] FDA's decision not to approve sotagliflozin for [T1d] patients prior to the Advisory Committee [Meeting],"[54] defendants argue that "Plaintiffs have failed to identify <u>any</u> information relevant to assessing the risk that FDA would not approve sotagliflozin that was not, in fact, disclosed."[55]

---

[53]<u>Id.</u> at 8 ¶ 20. <u>See also id.</u> at 46-47 ¶ 137 ("Throughout the Class Period, Lexicon and the Individual Defendants made false and/or misleading statements and/or omissions that (i) minimized the risks of DKA associated with sotagliflozin; (ii) misrepresented that the purported benefits of sotagliflozin would outweigh the risks of DKA; (iii) failed to disclose that the Time-in-Range and Glycemic Variability measures touted by Lexicon had not been validated for use in regulatory decision making for antidiabetic drugs; (iv) failed to disclose that Lexicon did not have a meaningful risk management plan for DKA; and (v) as a result, Lexicon's public statements were materially false and misleading at all relevant times. These false and/or misleading statements and/or omissions created a false impression of the likelihood that the Advisory Committee would recommend that the FDA approve sotagliflozin.").

[54]Defendants' Motion to Dismiss, Docket Entry No. 33, p. 18.

[55]<u>Id.</u> <u>See also id.</u> at 18-27 (arguing that Lexicon did not (continued...)

Citing inter alia Nathenson v. Zonagen, Inc., 267 F.3d 400, 420 (5th Cir. 2001), defendants argue that

> [t]he overwhelming weight of authority . . . holds that the securities laws do not require a company to disclose alleged inadequacies or shortcomings of clinical trials, as long as the trials are accurately described and the data is not falsified.[56]

Plaintiffs respond that they have pleaded actionable misstatements and omissions by alleging that defendants (1) failed to disclose FDA warnings against the composite endpoint, (2) misrepresented the extent and severity of DKA, (3) misrepresented the benefits of sotagliflozin, (4) failed to fully disclose that "time-in-range" was not a validated endpoint, and (5) mislead investors about their risk management protocol.[57] Asserting that FACAC "does allege actionable misstatements," plaintiffs argue that defendants' SOX certifications are also actionable.[58]

---

[55](...continued)
conceal an FDA warning, accurately disclosed its trial results, the limitations of its DKA risk management plan, that "Time-in-Range" was not a validated endpoint, and that SOX Certifications are not independently actionable).

[56]Defendants' Reply, Docket Entry No. 37, p. 17.

[57]Plaintiffs' Opposition, Docket Entry No. 35, pp. 16-27.

[58]Id. at 27.

(1) Plaintiffs' Allegations that Defendants Failed to Disclose FDA Warnings against the Composite Endpoint Are Not Actionable

Citing the transcript of the Advisory Committee Meeting held on January 17, 2019, the FACAC alleges defendants reported that sotagliflozin achieved a composite endpoint but misleadingly failed to disclose that the FDA had expressed concern about whether the composite endpoint would be adequate to characterize the overall benefit-risk on eight different occasions, i.e., in two Form 10-Ks filed with the SEC in March of 2018 and 2019 for fiscal years 2017 and 2018, respectively, and in six press releases issued on May 11, 2017, June 9, 2017, August 15, 2017, September 13, 2017, and June 23 and 24, 2018.[59] The FACAC alleges that

> [t]o obtain results in the Phase 3 Trials that emphasized the purported benefits of sotagliflozin and minimized the risk of DKA, Defendants designed a "composite endpoint" as the secondary endpoint in the inTandem1 and inTandem2 trials and the primary endpoint for the inTandem3 trial. The composite endpoint measured the "proportion of patients who achieved an A1c of less than 7% without an episode of severe hypoglycemia or DKA." By reporting the amount of patients who achieved an HbA1c level below 7% without an episode of severe hypoglycemia or DKA, however, the composite endpoint reported the incidence of a catastrophic, life-threatening condition in the context of how many more patients were benefitting from the drug.
>
> Unbeknownst to investors, "[d]uring presubmission **meetings** with the sponsor, the FDA expressed concern about the utility of the composite endpoint and **whether it would be adequate to characterize the overall benefit-risk"** of sotagliflozin. Comm. Tr. 118:15-19. As is the general practice in clinical testing of proposed medications, the FDA met with Defendants prior to the start of the Phase 3 Trials in 2015 to discuss the content of those trials. Moreover, the FDA also met with Defendants in the lead-up to the submission

[59]FACAC, Docket Entry No. 27, pp. 53-56 ¶¶ 153-61.

> of the sotagliflozin NDA in March 2018. Thus, as early as 2015, and in any event by March 2018, at the latest, Defendants had actual knowledge that the FDA was not in favor of the composite endpoint used by Lexicon in its Phase 3 Trials, and that the composite endpoint did not "actually assess the net benefit of the product or help inform the overall benefit-risk assessment," Comm. Tr. 126:2-7, 127:14-18, and thus that the Advisory Committee was unlikely to vote that the benefits of sotagliflozin outweighed the risks and the FDA was unlikely to approve the drug. While Defendants repeatedly touted to investors throughout the Class Period that the Phase 3 Trials had achieved the composite endpoint, Defendants never disclosed the FDA's concerns to investors.[60]

The FACAC alleges that defendants' statements about having achieved the composite endpoint

> [a]s set forth in ¶¶ 153-160 . . . were false and misleading because Defendants had failed to disclose that (i) they had [] devised the composite endpoint to highlight the benefits of sotagliflozin while concealing the risks of DKA, (ii) the FDA has expressed concerns [about] the composite endpoint . . . multiple times, and (iii) that the composite endpoint "does not actually assess the net benefit of the product or help inform the overall benefit-risk assessment." Comm. Tr. 126:2-7, 127:14-18.[61]

Asserting that plaintiffs provide no facts to back up their allegation that the FDA warned them about the composite endpoint, defendants argue that the FACAC's allegations that they failed to disclose an FDA warning should be dismissed because they are not sufficient to state a claim for securities fraud by omission.[62] Defendants also argue that they had no duty to disclose an FDA

[60] Id. at 53-54 ¶¶ 153-54 (quoting Advisory Committee Meeting Transcript, pp. 118:15-19, 126:2-7, 127:14-18, Exhibit 8 to Defendants' Motion to Dismiss, Docket Entry No. 34-15, pp. 119, 127-28).

[61] Id. at 56 ¶ 161 (quoting Advisory Committee Meeting Transcript, pp. 126:2-7, 127:14-18, Exhibit 8 to Defendants' Motion to Dismiss, Docket Entry No. 34-15, pp. 127-28).

[62] Defendants' Motion to Dismiss, Docket Entry No. 33, pp. 22-24.

concern because the composite endpoint was only a secondary not a pivotal endpoint, and because the FDA's statement at the Advisory Committee Meeting "proves only that reasonable scientists can disagree about the probative value of an endpoint."[63]

Citing In re Amylin Pharmaceuticals, Inc. Securities Litigation, 2003 WL 21500525, at *8 (S.D. Cal. May 1, 2003), In re CV Therapeutics, Inc. Securities Litigation, No. C 03-03709 SI, 2004 WL 1753251, at *8-*9 (N.D. Cal. August 5, 2004), and In re Transkaryotic Therapies, Inc. Securities Litigation, 319 F.Supp.2d 152, 160 (D. Mass. 2004), plaintiffs argue that "[w]hen the FDA expresses significant concerns regarding sufficiency of clinical trials, those concerns must be disclosed."[64]

The FACAC's allegations that the defendants committed securities fraud by omission by failing to disclose (i) that the composite endpoint was designed to highlight the benefits of sotagliflozin while concealing the risks of DKA, (ii) that the FDA had concerns about the composite endpoint, and (iii) that the composite endpoint did not actually assess the net benefit of the product or help inform the overall benefit-risk assessment are based on statements made at the Advisory Committee Meeting held on January 17, 2019,[65] long

---

[63]Defendants' Reply, Docket Entry No. 37, pp. 11-14. See also id. at 14-17 (arguing that plaintiffs fail to adequately allege FDA concerns and that defendants had no duty to disclose interim comments from the FDA on a non-pivotal secondary endpoint).

[64]Plaintiffs' Opposition, Docket Entry No. 35, p. 16.

[65]Id. at 17-18 (citing FACAC, Docket Entry No. 27, pp. 39-40 (continued...)

after defendants made all but one of the statements about the composite endpoint that the FACAC alleges were misleading. The only statement about having achieved the composite endpoint alleged to have been made after the Advisory Committee Meeting is the statement included in Lexicon's 2018 Annual Report filed with the SEC on Form 10-K on March 15, 2019.[66] Because the information that plaintiffs allege defendants failed to disclose was, in fact, publicly disclosed during the Advisory Committee Meeting, the failure to disclose that information in Lexicon's 2018 Annual Report filed in March 2019, almost two months after the Advisory Committee Meeting, could not have made statements about the composite endpoint contained in Lexicon's 2018 Annual Report misleading.

Missing from the FACAC, however, are allegations of facts capable of showing that the composite endpoint was, in fact, designed to highlight the benefits of sotagliflozin while concealing the risks of DKA, or that when defendants made the statements alleged to be misleading there existed any information that the composite endpoint did not assess the net benefit of sotagliflozin and would not help inform the overall benefit-risk

---

[65](...continued)
¶ 116, 54 ¶ 154, and 70 ¶ 205).

[66]FACAC, Docket Entry No. 27, pp. 55-56 ¶ 159 (stating that there were "statistically significant improvements . . . in the percentage of patients achieving A1c levels of less than 7% without any severe hypoglycemia or DKA events").

assessment. The FACAC's allegations that defendants' statements about the composite endpoint were misleading are based a statement made by an FDA representative at the Advisory Committee Meeting that "[d]uring presubmission meeting with the sponsor, the FDA expressed concern about the utility of the composite endpoint and whether it would be adequate to characterize the overall benefit-risk [of sotagliflozin]."[67] Missing from the FACAC, however, are allegations of facts showing when, where, to whom, or how the FDA raised its concern about the composite endpoint. Citing the FACAC's allegations that Lexicon planned the phase 3 trials in 2015, and that Sanofi submitted the NDA in March 2018, plaintiffs argue that the FDA's concern had to have been raised to the sponsor sometime between 2015 and 2018.[68] As defendants argue, however, "[t]he date of the alleged warning is critical because [p]laintiffs cannot argue that a statement was misleading on the basis of a warning given after that statement was made."[69] Since, moreover, the FDA representative told the Advisory Committee that the concern was raised to the "sponsor," and the FACAC alleges that the sponsor was Sanofi, not Lexicon,[70] the FACAC does not contain allegations

---

[67]Plaintiffs' Opposition, Docket Entry No. 35, p. 17 (citing FACAC, Docket Entry No. 27, pp. 39-40 ¶ 116).

[68]Id. (citing FACAC, Docket Entry No. 27, pp. 54 ¶ 154, and 70 ¶ 205).

[69]Defendants' Reply, Docket Entry No. 37, p. 16 (emphasis added).

[70]FACAC, Docket Entry No. 27, p. 34 ¶ 100 (identifying Sanofi (continued...)

of fact showing that an FDA concern about the composite endpoint was ever raised to the defendants.

Asserting that "[a]ny suggestion that the FAC[AC] only alleges a warning to Sanofi, and not Lexicon, should be rejected," plaintiffs argue in a footnote that

> [i]t is not plausible that FDA feedback on the Phase 3 Trials would not reach [d]efendants, who were solely responsible for the trials, when Coats was promising that the trials addressed FDA expectation. The Court would have to infer that Sanofi did not share warnings with Defendants that put Sanofi's investment of hundreds of millions of dollars at risk.[71]

The court reads this footnote as plaintiffs' acknowledgment that the FACAC does not allege facts capable of establishing that the FDA concern was raised to the defendants.

Because the FACAC does not contain facts showing when, where, to whom, or how the FDA concern about the composite endpoint was communicated, the FACAC's allegations that defendants' statements about having achieved a composite endpoint were false and misleading for having failed to disclose an FDA concern are not sufficiently particularized to state claims for securities fraud by omission. See Gerneth v. Chiasma, No. 16-11082, 2018 WL 935418, *7 (D. Mass. February 15, 2018) ("At the very least, [the plaintiff] must plead that the information did exist to allege plausibly that

---

[70](...continued) as the sponsor of the NDA for sotagliflozin).

[71]Plaintiffs' Opposition, Docket Entry No. 35, p. 19 n. 7.

[d]efendants should have disclosed it.") (citing Gross v. Summa Four, Inc., 93 F.3d 987, 995 (1st Cir. 1996) (superseded by statute on other grounds) (rejecting argument that press release was misleading based on reference to information contained in board minutes created after the press release was issued)).

While the Fifth Circuit has recognized that "evidence of later events can provide useful circumstantial evidence that a given representation was false when made," Masel v. Villarreal, 924 F.3d 734, 750 (5th Cir. 2019), the Fifth Circuit explained that such an inference could be raised when "the representation in question concerned an asset or skill possessed by the defendant . . ., [and] the defendant's failure to perform as promised cast doubt on whether the defendant possessed that skill in the first place." Id. Plaintiffs have not cited and the court has not found any authority that has accepted a vague reference to an earlier communication — such as the reference made at the Advisory Committee Meeting — as sufficient to allege that statements made by the defendants months and years earlier were false or misleading when made. The cases plaintiffs cite in support of their omission theory regarding an FDA concern about the composite endpoint are illustrative and bolster the court's conclusion that the FACAC's allegations regarding the defendants' failure to disclose an FDA concern are not sufficient to allege actionable omissions.

In each of the cases on which plaintiffs rely the allegations were found sufficient to allege actionable omissions because plaintiffs pleaded facts showing that when the defendants made the allegedly misleading statements, those statements were directly contradicted by undisclosed information available to the defendants. In Amylin the court found that plaintiffs had adequately pleaded an actionable omission by alleging that the defendants publicly advertised the FDA's approval of its phase 3 trial methodology while omitting that the FDA had in fact highlighted particular ways in which its methodology was "inconsistent with clinical practice" and would therefore be difficult for the FDA to evaluate. 2003 WL 21500025, at *1 and *8. The Amylin court also found that the plaintiffs adequately pleaded actionable omissions by alleging that defendants publicly reported that successful results were obtained without an increase in severe hypoglycemic events when, in fact, the company knew that severe hypoglycemia was a significant side effects. Id. at *10. Likewise, in each of the other cases plaintiffs cite, the courts held that the plaintiffs adequately pleaded actionable omissions by quoting from specifically identified and dated communications that the FDA had provided to the defendants stating, inter alia, that the FDA found major deficiencies pertaining to the company's clinical studies, In re CV Therapeutics, Inc. Securities Litigation, 2004 WL 1753251, at *1, and that the FDA had

recommended additional clinical studies. In re Transkaryotic Therapies, Inc. Securities Litigation, 319 F.Supp.2d at 160.

Citing Stone v. Life Partners Holdings, Inc., 26 F.Supp.3d 575, 604 (W.D. Tex. 2014), plaintiffs argue that "the FAC[AC]'s reference to the specific FDA report disclosing the warning is sufficient to defeat a motion to dismiss."[72] But because the FACAC does not reference a specific FDA report disclosing the warning, Stone is distinguishable and does not support the plaintiffs' argument. In Stone the plaintiffs alleged that the defendants' statements were misleading because they were contradicted by information contained in specifically identified and dated reports that were not only created by the defendant company, but were on file with the Texas Department of Insurance when the defendants made the statements at issue. Id. at 602-04. The FACAC contains no such particularized allegations of the FDA's alleged concern.

The allegations in the FACAC are, instead, comparable to those at issue in Hoey v. Insmed Inc., Civil Action No. 16-4323 (FLW), 2018 WL 902266 (D.N.J. February 15, 2018), on which the defendants rely. In Hoey the court dismissed a securities fraud claim based on allegations that the defendants failed to disclose a regulatory warning about a pre-defined endpoint because the complaint cited only a description of the regulator's communication to the defendants and failed to cite an actual communication from the

[72]Id. at 19.

regulator capable of showing that the defendants were aware of the regulator's concerns when they made the statements at issue. Id. at *13 (citing Fed.R.Civ.P. 9(b) ("In all averments of fraud or mistake, the circumstances constituting fraud or mistake shall be stated with particularity.")). Because plaintiffs in this case fail to cite an actual communication from the FDA to the defendants showing that when the defendants made the statements about the composite endpoint alleged to be misleading, the FDA's concerns were available to them, the defendants' statements are not actionable as false or misleading, and the defendants' failure to disclose those concerns are not actionable omissions. Alternatively, for the reasons stated in § II.B.1(b), below, the court concludes that defendants' composite endpoint-related statements are not actionable because plaintiffs have failed to plead facts capable of establishing a strong inference that defendants made any of the alleged statements with scienter.

(2) Plaintiffs' Allegations that Defendants Misrepresented the Extent and Severity of DKA Are Not Actionable

Citing FDA briefing materials provided to the Advisory Committee and the transcript of the Advisory Committee Meeting held on January 17, 2019, plaintiffs argue that defendants misleadingly minimized the risk of DKA presented by sotagliflozin on 15 different occasions, i.e., four Form 10-Ks filed with the SEC in March of 2016, 2017, 2018, and 2019; six Press Releases issued on

September 9, 2016, December 21, 2016, May 11, 2017, September 13, 2017, and June 23 and 24, 2018; three Earnings Calls held on August 4, 2016, September 9, 2016, and November 8, 2017; and two presentations at conferences held on January 11, 2017, and January 9, 2019.[73] Plaintiffs do not allege that defendants falsely reported the number of incidences of DKA, but, instead, that

> throughout the Class Period Defendants minimized risks of DKA associated with sotagliflozin by downplaying the incidences of the life threatening condition and by failing to disclose that patients taking sotagliflozin in the Phase 3 Trials had experienced an **eightfold increase** in the incidence of DKA, that those incidences of DKA were **severe,** that steps taken to address the incidence of DKA **did not affect the incidence of DKA,** that incidences of DKA in Phase 3 Trials were difficult to identify, and that the incidence of DKA was likely **suppressed by the clinical setting** of the Phase 3 Trials.[74]

Asserting that Lexicon accurately disclosed its trial results, defendants argue that "the very information that [p]laintiffs claim was misstated or omitted from communications to investors and [the] FDA was disclosed clearly and repeatedly . . . in advance of the alleged corrective disclosures."[75] Asserting "[p]laintiffs do not allege that Lexicon possessed internally any data different from the data they disclosed or that any of the data Lexicon reported was false," defendants argue that "[p]laintiffs have failed to state a claim for fraud."[76]

---

[73]FACAC, Docket Entry No. 27, pp. 47-53 ¶¶ 138-152.

[74]Id. at 47 ¶ 138.

[75]Defendants' Motion to Dismiss, Docket Entry No. 33, p. 19.

[76]Id. at 19-20. See also Defendants' Reply, Docket Entry
(continued...)

Citing Rubinstein v. Collins, 20 F.3d 160, 170 (5th Cir. 1994), for holding that "a duty to speak the full truth arises when a defendant undertakes a duty to say anything," plaintiffs argue that defendants' statements concerning DKA were misleading because defendants described the incidence of DKA during the phase 3 tests as "slight," "manageable," or "low," when in fact there was an eightfold increase in DKA that was severe, difficult to diagnose, resistant to management, and likely understated.[77] Citing Public Employees' Retirement System of Mississippi, Puerto Rico Teachers Retirement System v. Amedisys, Inc., 769 F.3d 313, 323 (5th Cir. 2014), cert. denied, 135 S. Ct. 2892 (2015), for its holding that "complex . . . data understandable only through expert analysis may not be readily digestible by the marketplace," plaintiffs argue that "[d]efendants' simple disclosure of complex raw clinical data is not sufficient to succeed on a motion to dismiss because that data has 'little to no probative value in its native state.'"[78]

The FACAC's allegations that defendants committed fraud by omission by failing to disclose an eightfold increase in the incidence of DKA that was more severe, difficult to diagnose, resistant to management and likely understated,[79] are based on statements made in

---

[76](...continued)
No. 37, pp. 17-20 (arguing that Lexicon accurately disclosed the design of and results from its clinical trials).

[77]Plaintiffs' Opposition, Docket Entry No. 35, pp. 19-20.

[78]Id. at 22.

[79]FACAC, Docket Entry No. 127, p. 47 ¶ 138.

briefing materials that the FDA provided to the Advisory Committee in advance of the Advisory Committee Meeting, and at the Advisory Committee Meeting held on January 17, 2019,[80] i.e., long after defendants made all but one of the statements about the extent and severity of DKA that the FACAC alleges were misleading. The only statement alleged to have been made after the Advisory Committee Meeting is the statement included in Lexicon's 2018 Annual Report filed with the SEC on Form 10-K on March 15, 2019.[81] Because the information that plaintiffs allege defendants failed to disclose was, in fact, publicly disclosed during the Advisory Committee Meeting, the failure to disclose that information in Lexicon's 2018 Annual Report filed in March 2019, almost two months after the Advisory Committee Meeting, could not have made statements about the extent and severity of DKA contained in Lexicon's 2018 Annual

[80]Plaintiffs' Opposition, Docket Entry No. 35, pp. 20-21 (citing FACAC, Docket Entry No. 27, pp. 10 ¶ 26, 36 ¶ 105 (quoting FDA Briefing Document as stating that "sotagliflozin therapy clearly increases that risk [of DKA], and the risk may be unpredictable"); 39 ¶ 115 (citing Sanofi meeting presentation as acknowledging at the meeting that patients "have less early signs and symptoms to detect emerging DKA"); 40 ¶ 117 (citing FDA statement that it needed to reformat the raw trial data to uncover **"the hidden trend"**) and ¶ 118 (citing FDA statements that incidence of DKA was likely suppressed in clinical setting); 41 ¶¶ 119-20 (citing FDA statements that interventions to reduce DKA during trials failed); 42 ¶ 122 (quoting a Committee Member as stating that "its not just that there is more DKA; it's the fact that it is more severe") and ¶ 123 (quoting a committee member as criticizing the structure of the trials by stating, "[w]e see only an instrument that is **heavily gamed** towards time in the therapeutic range of the drug")).

[81]FACAC, Docket Entry No. 27, pp. 51-52 ¶¶ 148-49.

Report misleading. Missing from the FACAC, however, are allegations of facts capable of showing that there was, in fact, an eightfold increase in DKA that was more severe, difficult to diagnose, resistant to management and likely understated, or that when defendants made the allegedly misleading DKA-related statements information existed that contradicted their statements.

(i) Plaintiffs' Allegations that Defendants Failed to Disclose an Eightfold Increase of DKA Are Not Actionable

The FACAC alleges that defendants issued press releases that publicly reported results for the inTandem1 trial in September 2016, May 2017, and June 2018; for the inTandem2 trial in December 2016 and June 2018; and for the inTandem3 trial in September 2017,[82] and that defendants disclosed additional information about these trial results in the Annual Reports that Lexicon filed on Form 10-Ks for 2016, 2017, and 2018 in March 2017, 2018, and 2019, respectively; in earnings calls held on August 4, 2016, September 9, 2016, and November 8, 2017; and in presentations at healthcare conferences held on January 11, 2017, and January 9, 2019. Although the FACAC alleges that defendants' described the incidences of DKA as "slight," "manageable," or "low," when in fact there was an eightfold increase in DKA that was severe, difficult

[82]Id. at 29 ¶ 87.

to diagnose, resistant to management, and likely understated,[83] the allegations in the FACAC and the statements challenged as misleading,[84] show that defendants disclosed detailed information about the DKA safety concern and the number of DKA incidences from which the fold increases of DKA could easily be calculated for each of the phase 3 trials. Because the fold increase of DKA could easily be calculated from the information disclosed, this case is distinguishable from Amedisys, 769 F.3d at 323, where "the hidden meaning of the . . . data required expert analysis," and "the data itself [wa]s only available to a narrow segment of the public," and the FACAC's allegations that defendants' characterization of the rate of DKA in those trials as "slight" or "low," are too vague to satisfy the requirements for pleading securities fraud with particularity.[85]

---

[83]Plaintiffs' Opposition, Docket Entry No. 35, p. 20.

[84]Plaintiffs did not attached copies of Lexicon's allegedly misleading disclosures to the FACAC, but many of them are before the court as exhibits to Defendants' Motion to Dismiss. Because courts may "rely on 'documents incorporated into the complaint by reference, and matters of which a court may take judicial notice,'" Dorsey, 540 F.3d at 338 (quoting Tellabs, 127 S. Ct. at 2509), the court may consider the alleged disclosures for the purpose of determining their contents but not for proving the truth of their contents without converting defendants' motion to dismiss to a motion for summary judgment. See Lovelace, 78 F.3d at 1018 & n.1. See also Wehlmann, 737 F. Supp. 2d at 616 (courts may consider "the full text of documents partially quoted in the complaint").

[85]The FACAC's allegations regarding defendants' statements that DKA could be managed are discussed in § II.B.1(a)(5), below.

(A) InTandem1 Trials

The FACAC alleges that on September 9, 2016, Lexicon issued a Press Release announcing that "sotagliflozin demonstrated compelling, significant and clinically meaningful A1C reduction with no increase in severe hypoglycemia and **a slight risk of DKA.**"[86] The FACAC alleges that the September 9, 2016, Press Release also stated that "[t]he number of patients with DKA events during [the inTandem1 Phase 3 Trial's] 24-week treatment period was 0 (0.0%), 3 (1.1%), and 8 (3.1%) in the placebo, 200mg and 400mg dose arms[, respectively]."[87] The FACAC alleges that the incidences of DKA for the 24-week treatment period of the inTandem1 Trial were repeated in the Annual Report for the Fiscal Year Ended December 31, 2016, that Lexicon filed with the SEC on Form 10-K in March 2017.[88]

The FACAC alleges that in a press release issued on May 11, 2017, defendants reported that

> "the rate of [DKA] during the 28-week extension period [of the inTandem phase 3 trial] was slightly higher than the rate seen in the initial 24-week treatment period for placebo (one patient, 0.4%) and the 200 mg dose arm (6, 2.5%) and lower for the 400 mg dose arm (3, 1.3%)." The press release also disclosed that "[t]he number of patients with DKA events during the full 52 weeks of

---

[86]FACAC, Docket Entry No. 27, p. 48 ¶ 141. See also September 9, 2016, Press Release, Exhibit 12 to Defendant's Motion to Dismiss, Docket Entry No. 34-19, p. 2.

[87]Id. See also September 9, 2016, Press Release, Exhibit 12 to Defendant's Motion to Dismiss, Docket Entry No. 34-19, p. 2.

[88]Id. at 49 ¶ 143. See also 2016 Annual Report, Form 10-K, p. 2, Exhibit 3 to Defendant's Motion to Dismiss, Docket Entry No. 34-3, p. 6.

treatment was 1 (0.4%), 9 (3.4%), and 11 (4.2%) in the placebo, 200 mg and 400 mg dose arms, respectively."[89]

The FACAC alleges that the incidences of DKA for the full 52-week treatment period of the inTandem1 Trial were repeated in the Annual Report for the Fiscal Year Ended December 31, 2017, that Lexicon filed with the SEC on Form 10-K in March 2018.[90]

Neither Lexicon's press releases nor its Annual Reports stated the fold increases of DKA incidences in the inTandem1 trials. Defendants argue — without objection from plaintiffs — that although the fold increase for the 24-week treatment cannot be calculated because the placebo arm did not experience any DKA events, the fold increases can easily be calculated for both the 28-week extension and the full 52-week treatment periods based on the disclosed information, i.e., by dividing the rate of DKA in the sotagliflozin arms by the rate of DKA in the placebo arms.[91] The equations for the 28-week extension period are thus: (1) the rate of DKA in the 200 mg dose arm (2.5%) ÷ the rate of DKA in the placebo arm (0.4%) = 6.25 for the 200 mg dose; and (2) the rate of DKA in the 400 mg dose arm (1.3%) ÷ rate of DKA in the placebo arm (0.4%) = 3.25 for the 400 mg dose. The equations for the full 52-week treatment period of the inTandem1 trial are: (1) rate of DKA

---

[89] Id. at 50 ¶ 145.

[90] Id. at 51 ¶ 148. See also 2017 Annual Report, Form 10-K, p. 3, Exhibit 4 to Defendant's Motion to Dismiss, Docket Entry No. 34-4, p. 6.

[91] Defendants' Motion to Dismiss, Docket Entry No. 33, p. 15 & nn. 17-19.

in the 200 mg dose arm (3.4%) ÷ rate of DKA in the placebo arm (0.4%) = 8.5 for the 200 mg dose; and (2) rate of DKA in the 400 mg arm (4.2%) ÷ rate of DKA in the placebo arm (0.4%) = 10.5 for the 400 mg dose.[92] Because information needed to calculate the allegedly omitted fold increases for the inTandem1 trials was disclosed, and that information showed fold increases that varied from a low of 3.25 for the 400 mg dose during the 28-week extension period, to a high of 10.5 for the 400 mg dose during the full 52-week treatment period, defendants' alleged failures to disclose an eightfold increase do not constitute actionable omissions with respect to the inTandem1 trials. See Gerneth, 2018 WL 935418, at *6 (holding that allegedly omitted percentages failed to state a claim because "[t]he information necessary to derive [those] percentages is either disclosed or calculable based on [disclosed] information").

(B) InTandem2 Trials

The FACAC alleges that on December 21, 2016, Lexicon issued a Press Release stating that "[t]he inTandem2 study demonstrated a **compelling safety and efficacy profile** for sotagliflozin in adults living with type 1 diabetes."[93] The FACAC also alleges the December

---

[92]See id. ("The publicly-released data from inTandem1 showed an 8.5 to 10.5-fold increase in DKA over placebo.").

[93]Id. at 49 ¶ 142. See also December 21, 2016, Press Release,
(continued...)

21, 2016, Press Release stated that "[t]he number of patients with DKA events during the 24-week treatment period was none (0.0%), one (0.4%), and three (1.1%) in the placebo, 200mg and 400mg dose arms respectively."[94] The FACAC alleges that the incidences of DKA in the inTandem2 Trial were repeated in the Annual Report for the Fiscal Year Ended December 31, 2016, that Lexicon filed with the SEC on Form 10-K in March 2017.[95] The FACAC alleges that the incidences of DKA for the full 52-week treatment period of the inTandem2 Trial were reported in the Annual Report for the Fiscal Year Ended December 31, 2017, that Lexicon filed with the SEC on Form 10-K in March 2018.[96] The 2017 Annual Report stated "[t]he number of patients with positively adjudicated DKA events during the full 52-week treatment period was 0 (0.0%), 6 (2.3%) and 9 (3.4%) in the placebo, 200mg and 400mg dose arms, respectively."[97] Defendants assert without objection from plaintiffs that because there were no incidences of DKA in the placebo arm of the inTandem2

---

[93](...continued)
p. 1, Exhibit 13 to Defendant's Motion to Dismiss, Docket Entry No. 34-20, p. 2.

[94]Id. See also December 21, 2016, Press Release, p. 2, Exhibit 13 to Defendant's Motion to Dismiss, Docket Entry No. 34-20, p. 3.

[95]Id. at 49 ¶ 143. See also 2016 Annual Report, Form 10-K, p.4, Exhibit 3 to Defendant's Motion to Dismiss, Docket Entry No. 34-3, p. 7.

[96]Id. at 51 ¶ 148.

[97]2017 Annual Report, Form 10-K, p. 3, Exhibit 4 to Defendant's Motion to Dismiss, Docket Entry No. 34-4, p. 6.

trials for either the 24- or 52-week treatment periods, calculating fold increases for those trials is not possible.[98] Therefore, defendants' alleged failures to disclose an eightfold increase in DKA incidences do not constitute actionable omissions with respect to the inTandem2 trials. See Gerneth, 2018 WL 935418, at *6.

(C) InTandem3 Trials

The FACAC alleges that on September 13, 2017,

> Lexicon issued a Press Release disclosing results from the inTandem3 trial . . . stat[ing] that "Sotagliflozin demonstrated a **generally well tolerated safety profile** during the 24-week treatment period," and that "[t]here was a higher rate of DKA during the 24-week treatment for sotagliflozin (3.0%) than placebo (0.6%)."[99]

The FACAC also alleges that DKA incidences in the 24-week treatment period of the inTandem3 Trial were repeated in the Annual Reports for the Fiscal Years ended December 31, 2017 and 2018 that Lexicon filed with the SEC on Form 10-Ks in March of 2018 and 2019.[100]

---

[98]Defendants' Motion to Dismiss, Docket Entry No. 33, p. 15 n. 19 ("Because the incidence of DKA in the placebo group was zero, a fold-increase cannot be calculated for this data.").

[99]FACAC, Docket Entry No. 27, p. 50 ¶ 146.

[100]Id. at 51-52 ¶ 148. See also 2017 Annual Report, Form 10-K, p. 4, Exhibit 4 to Defendant's Motion to Dismiss, Docket Entry No. 34-4, p. 7 ("The number of patients with positively adjudicated DKA events during the 24-week treatment period was 4 (0.6%) and 21 (3.0%) in the placebo and 400mg dose arms, respectively. Results from the inTandem3 trial were published in the New England Journal of Medicine in September 2017."); 2018 Annual Report, Form 10-K, p. 7, Exhibit 1 to Plaintiffs' Opposition, Docket Entry No. 36-1, p. 8 (same as from 2017 Form 10-K).

Although neither the September 13, 2017, Press Release, nor Lexicon's 2017 or 2018 Annual Reports disclosed a fold increase for in DKA incidences experienced during the inTandem3 trials, those increases are easily calculated from the information disclosed by dividing the rate of DKA in the sotagliflozin arm (3.0%), by the rate of DKA in the placebo arm (0.6%) = 5.[101] Because the information disclosed from the inTandem3 trials showed a five fold increase in DKA over placebo, defendants' alleged failures to disclose an eightfold increase do not constitute actionable omissions with respect to the inTandem3 trials.

(ii) Plaintiffs' Allegations that Defendants Failed to Disclose the Severity and Difficulty to Identify and Manage DKA Are Not Actionable

Asserting that "[d]efendants also misrepresented the results of the Phase 3 Trials by not informing investors of the spike in severe DKA that set in without usual warning signs and was not affected by [d]efendants' risk management protocols,"[102] plaintiffs argue that "[d]efendants statements concerning DKA were plainly misleading."[103] The DKA-related information that plaintiffs allege

[101]Defendants' Motion to Dismiss, Docket Entry No. 33, p. 15 & n. 17. Unlike the inTandem 1 and 2 trials, the inTandem3 trials did not have a 200 mg dose arm.

[102]Plaintiffs' Opposition, Docket Entry No. 35, p. 19.

[103]Id. at 20.

defendants misleadingly failed to disclose derives from briefing materials that the FDA provided to the Advisory Committee and on comments made at the Advisory Committee Meeting held on January 17, 2019. For example, plaintiffs cite FACAC ¶ 26 which alleges that

> [a]t the Committee Meeting, on January 17, 2019, the FDA bluntly told the Committee that "sotagliflozin was associated with an approximately eightfold increase in DKA risk versus placebo," which was likely understated because "in the clinical trial setting, patients receive intensive clinical monitoring." See Comm. Tr. 144:3-14. The FDA also called out the misleading endpoint used by Defendants in the Phase 3 Trials, telling the Advisory Committee that "[s]ponsor defined net benefit [i.e., composite endpoint] **masked increased risk in DKA** in sotagliflozin groups." Id. 126:2-7.[104]

Plaintiffs also argue that

> Defendant Lapuerta . . . expressly misled investors by advising to look beyond the incidence of DKA by putting that incidence into "context," when he should have advised investors that the incidence showed an increase in severe DKA episodes that were difficult to diagnose and manage.
>
> Similarly, [d]efendants' statements about sotagliflozin being "well tolerated" and "most important[ly] . . . there was very little discontinuation," gave investors the impression that the trials showed that sotagliflozin was safe and effective when the FDA and Committee's statements show that the opposite was true. See ¶ 105 ([quoting FDA briefing materials as stating that] "sotagliflozin therapy clearly increases that risk [of DKA], and the risk may be unpredictable"); ¶ 115 ([citing Sanofi meeting presentation as stating that] "patients 'have less early signs and symptoms to detect emerging DKA'"); ¶ 118 ([citing FDA statements that] DKA [was] likely suppressed in clinical setting); ¶¶ 119-20 ([citing FDA statements that] interventions to reduce DKA during trials failed); ¶ 122 ([quoting a Committee Member as stating that] "its

[104]FACAC, Docket Entry No. 27, p. 10 ¶ 26.

> not just that there is more DKA; it's the fact that it is more severe"). The FDA noted that it needed to reformat the raw trial data to uncover the "hidden trend" of DKA increases. ¶ 117. [One] Committee [Member] also said that "[w]e only see an instrument that is heavily gamed towards time in the therapeutic range of the drug." ¶ 123 (emphasis added). Finally, the FDA and Committee's hostile reaction to Phase 3 Trial Data underscores that [d]efendants' positive statements about that data were false and misleading.[105]

Missing from the FACAC, however, are allegations of facts showing when, where, or how information about the severity of the incidences of DKA that occurred during the phase 3 trials, or the difficulty in identifying or managing those incidences became known or available to the defendants. For example, the FACAC does not allege that the allegedly omitted information was contained in undisclosed internal analyses or communications that contradicted the defendants' public statements. Also missing are allegations of fact showing that information contradicting the defendants' DKA-related statements was available to the defendants when they made the statements alleged to be misleading, i.e., at any time before the Advisory Committee Meeting. Plaintiffs' assertion that the FDA "needed to reformat the raw trial data to uncover the 'hidden trend' of DKA increases,"[106] undermines any inference that defendants fraudulently failed to disclose information that was

[105]Plaintiffs' Opposition, Docket Entry No. 35, pp. 20-21 (citing FACAC, Docket Entry No. 27, pp. 36 ¶ 105, 39 ¶ 115, 40 ¶¶ 117-18, 41 ¶¶ 119-20, 42 ¶¶ 122-23).

[106]Id. at 21 (citing FACAC, Docket Entry No. 27, p. 40 ¶ 117).

available when they made the allegedly misleading statements. These allegations also bolster defendants' contention that the Advisory Committee's "discussion centered around 'varying interpretations' of clinical data, a risk that Lexicon had warned its investors might prevent regulatory approval."[107]

Nor does the FACAC contain any allegations of fact showing that defendants created a duty to disclose information about the severity or difficulty to identify or manage the incidences of DKA that occurred during the phase 3 trials by commenting or suggesting that incidences of DKA were not severe, or not difficult to identify or manage. To the contrary, virtually every disclosure alleged to be misleading for which the entire text has been provided to the court addresses the significance the risk of DKA poses to T1d patients. For example, the September 9, 2016, press release and Lexicon's 2016 Annual Report filed on Form 10-K in March of 2017 both state that DKA was a primary safety concern for T1d patients.[108] Moreover, the FACAC alleges that DKA is a serious, life-threatening condition,[109] that the increased risk of DKA caused

---

[107]Defendants' Motion to Dismiss, Docket Entry No. 33, p. 16.

[108]See September 9, 2016, Press Release, p. 2, Exhibit 12 to Defendants' Motion to Dismiss, Docket Entry No. 34-19, p. 3 ("Two primary safety concerns for patients with type 1 diabetes are severe hypoglycemia and diabetic ketoacidosis (DKA)."); 2016 Annual Report, Form 10-K, p. 3, Exhibit 3 to Defendants' Motion to Dismiss, Docket Entry No. 34-3, p. 6 ("Two primary safety concerns for patients with type 1 diabetes are severe hypoglycemia and diabetic ketoacidosis, or DKA.").

[109]FACAC, Docket Entry No. 27, pp. 3 ¶ 7, and 22 ¶ 68.

by SGLT drugs like sotagliflozin was well known before the start of the phase 3 trials both from sotagliflozin's phase 2 trials,[110] and from a labeling requirement that the FDA imposed on a SGLT medication approved shortly before the phase 3 trials for sotagliflozin began.[111] These allegations contained in the FACAC undermine the plausibility of the plaintiffs' claim that defendants' reports of results from the phase 3 trials mislead investors to believe that an increased risk of DKA would not be important to the FDA.

The plausibility of the FACAC's allegations that defendants' failure to disclose that the incidences of DKA that occurred during the phase 3 trials were severe and difficult to identify and manage, misled investors is also undermined by the fact that the significance the DKA risk would have for FDA approval of sotagliflozin was raised by an analyst and acknowledged by defendants during the August 4, 2016, earnings call in which plaintiffs allege Lapuerta misleadingly minimized the DKA risk. During that call an analyst asked, "there are approved SGLT2's on the market that have had some DKA. What do you think of as an acceptable rate in the context of A1c benefit?"[112] In pertinent

---

[110]Id. at 24 ¶ 74 ("Based on the FDA's statements of concern about the incidence of DKA in SGLT-2 inhibitors, [d]efendants knew that significant incidences of DKA could cause the FDA to not approve the drug because DKA was so substantial a health risk for diabetes sufferers.").

[111]Id. at 23 ¶¶ 70-71 & nn. 18-19.

[112]August 4, 2016, Earnings Call Transcript, p. 8, Exhibit 16 (continued...)

part Lapuerta responded by acknowledging that DKA is common in T1d, and that he expected to see it in any T1d program. He also said,

> [w]e remain blinded to our results. We do believe that some therapies have increased risk of DKA. One of the therapies that have an increased risk of DKA but is very acceptable to patients is the use of pumps. Pumps malfunction, insulin pumps. As so we do think that there is a window and that there is an acceptable range that you could have some DKA but still have a proposition that's very favorable to patients. And I think one of the most important propositions that we're looking to is to see whether or not we can improve time and range, which for patients would mean ultimately a lower risk of hypoglycemia, and that's a big issue to patients.[113]

When pressed about what he would consider to be an acceptable range of DKA, Lapuerta stated:

> I'd rather not comment on the range because I think it depends on the context. And that's one of the things I encourage you to look at not just the DKA, but take the DKA into context with other events like A1c reduction and incidence of severe hypoglycemia, and mild-to-moderate hypoglycemia. All of these come together, and I think because of that, it's difficult to provide an exact range for one event, when there are three others that need to be taken into account.[114]

Plaintiffs allege that Lapuerta's statement was misleading because "it suggested to investors that the incidence of DKA was not important, when, in fact, the eightfold increase in incidences of DKA during the Phase 3 Trials would matter most to the Advisory Committee and the FDA."[115]

---

[112](...continued)
to Defendants' Motion to Dismiss, Docket Entry No. 34-23, p. 9.

[113]Id. at 9, Docket Entry No. 34-23, p. 10.

[114]Id.

[115]FACAC, Docket Entry No. 27, pp. 47-48 ¶ 140. See also
(continued...)

Lapuerta's comments during the August 4, 2016, earnings call did not minimize the importance that an increased risk of DKA posed to the FDA approval process but, instead, encouraged listeners to consider those risks together with other measures including the reduction of A1c and the incidences of severe hypoglycemia. Because the FACAC alleges that "[w]hether a drug is shown to reduce HbA1c levels is a key factor in whether the drug will be approved to treat diabetes,"[116] and recognizes hypoglycemia as one of two life-threatening conditions for diabetics — the other being DKA,[117] and because reduction in A1c was the primary endpoint of the inTandem1 and inTandem2 trials,[118] and the incidences of severe hypoglycemia and DKA were accounted for in the composite

---

[115](...continued) Plaintiffs' Opposition, Docket Entry No. 35, p. 20 (asserting that Lapuerta "misled investors by advising to look beyond the incidence of DKA by putting that incidence into 'context,' when he should have advised investors that the incidence showed an increase in severe DKA episodes that were difficult to diagnose and manage").

[116]FACAC, Docket Entry No. 27, p. 21 ¶ 66.

[117]Id. at 7 ¶ 17 (recognizing hypoglycemia as "a different life-threatening condition for diabetics that is caused by low blood sugar"). See also September 9, 2016, Press Release, p. 2, Exhibit 12 to Defendants' Motion to Dismiss, Docket Entry No. 34-19, p. 3 ("Two primary safety concerns for patients with type 1 diabetes are severe hypoglycemia and diabetic ketoacidosis (DKA)."); 2016 Annual Report, Form 10-K, p. 3, Exhibit 3 to Defendants' Motion to Dismiss, Docket Entry No. 34-3, p. 6 ("Two primary safety concerns for patients with type 1 diabetes are severe hypoglycemia and diabetic ketoacidosis, or DKA.").

[118]Id. at 25 ¶ 75 ("Defendants set the 'primary endpoint' of the inTandem1 and inTandem2 trials as the 'change from baseline in HbA1c by week 24 of the trial.'").

endpoint,[119] Lapuerta's comments were not misleading but, instead, reasonably consistent with the FACAC's allegations regarding both the design of the phase 3 trials and the available data. See Abrams v. Baker Hughes, Inc., 292 F.3d 424, 433 (5th Cir. 2002) (quoting Novak v. Kasaks, 216 F.3d 300, 309 (2d Cir.), cert. denied, 121 S. Ct. 567 (2000) ("As long as public statements are reasonably consistent with available data, corporate officials need not present an overly gloomy or cautious picture of the company's current performance or future prospects."). Moreover, plaintiffs do not argue, and the FACAC does not allege, that on August 4, 2016, when Lapuerta made the allegedly misleading comment he could possibly have known either that the phase 3 trials would result in an eightfold increase in incidences of DKA, that the incidences of DKA would be severe, difficult to diagnose and manage, or that the "eightfold increase in incidences of DKA during the Phase 3 Trials would matter most to the Advisory Committee and the FDA."[120] Accordingly, the court concludes that Lapuerta's comments during the August 4, 2016, earnings call are not actionable misrepresentations.

---

[119]Id. at 5 ¶ 10 (recognizing that the "'composite endpoint' . . . measured 'the proportion of patients who achieved an A1c of less than 7% without an episode of severe hypoglycemia or DKA'").

[120]Id. at 48 ¶ 140.

Because the FACAC fails to allege facts showing when, where, or how information became available regarding the severity of the DKA incidences that occurred during the phase 3 trials, or how difficult those incidences were to diagnose or manage, the FACAC does not contain allegations of fact capable of establishing that when defendants made their allegedly misleading statements about the incidences of DKA, defendants failed to disclose any existing and available contradictory information. The FACAC's allegations that defendants' DKA-related statements were misleading because they failed to disclose that incidences of DKA were severe and difficult to diagnose or manage are not sufficiently particularized to state claims for securities fraud by omission. See Gerneth, 2018 WL 935418, at *7 ("At the very least, [the plaintiff] must plead that the information did exist to allege plausibly that [d]efendants should have disclosed it.") (citing Gross, 93 F.3d at 995 (rejecting argument that press release was misleading based on reference to information contained in board minutes created after the press release was issued)). Alternatively, for the reasons stated in § II.B.1(b), below, the court concludes that defendants' DKA-related statements are not actionable because plaintiffs have failed to plead facts capable of establishing a strong inference that defendants made any of the alleged statements with scienter.

(3) Plaintiffs' Allegations that Defendants Misrepresented the Benefits of Sotagliflozin Are Not Actionable

The FACAC alleges that defendants misrepresented the benefits of sotagliflozin on eight different occasions, i.e., in four different Form 10-Ks filed with the SEC in March of 2016, 2017, 2018, and 2019, and in four Press Releases issued on September 9, 2016, December 21, 2016, and June 23 and 24, 2018.[121] The FACAC does not allege that defendants made any false statements about the design or results of the phase 3 trials but, instead, alleges that

> [d]efendants misrepresented the benefits of sotagliflozin throughout the Class Period by (i) structuring the Phase 3 Trials to misleadingly emphasize reductions in HbA1C levels and downplay incidences of DKA, (ii) touting decreases in HbA1c levels knowing that those levels would not necessarily be meaningful for patients with starting HbA1c levels over 8%, (iii) touting weight reductions without disclosing that those reductions were under 5% of the patient's body weight and thus not clinically significant, and (iv) downplaying the incidences of DKA.[122]

The FACAC alleges that

> [t]hese disclosures were materially misleading because they failed to disclose that the mean decreases in HbA1c were not meaningful and thus did not outweigh the serious risk of severe DKA, the incidence of which increased eightfold over placebo in the Phase 3 trials. These statements were also false and misleading because [d]efendants failed to disclose that the composite endpoint emphasized the modest benefits of sotagliflozin while concealing the risks of DKA.[123]

---

[121] Id. at 56-61 ¶¶ 162-73.

[122] Id. at 61 ¶ 173. See also id. at 56-57 ¶ 162 (virtually identical allegations).

[123] Id. at 59-61 ¶¶ 168-71 (the quoted sentence is repeated in (continued...)

Defendants argue that plaintiffs allegations that they misrepresented the benefits of sotagliflozin should be dismissed because "Lexicon disclosed accurately the benefits of sotagliflozin, including A1c reduction, weight loss, and the effect of hypoglycemia."[124] Defendants also argue that the statements the FACAC challenges reflect only inactionable "disagree[ment] about how to interpret the results."[125]

Plaintiffs respond that "[d]efendants misleadingly touted trial results showing decreases in A1c, incidence of hypoglycemia and patient weight, even though [d]efendants knew that those decreases were not necessarily meaningful."[126] Citing McNamara v. Bre-X Minerals Ltd, 197 F. Supp. 2d 622, 686-87 (E.D. Tex. 2001), plaintiffs argue that "[i]n touting the positive results of Phase 3 Trials, [d]efendants undertook an obligation to fully disclose all facts necessary to make their statements not misleading."[127] Citing Schueneman v. Arena Pharmaceuticals, Inc., 840 F.3d 698, 709

---

[123](...continued)
each of the cited paragraphs).

[124]Defendants' Motion to Dismiss, Docket Entry No. 33, p. 21.

[125]Id. See also Defendants' Reply, Docket Entry No. 37, pp. 17-22 (arguing that plaintiffs' allegations defendants misrepresented the benefits of sotagliflozin should be dismissed because plaintiffs have conceded that Lexicon accurately disclosed the design and results of its clinical trials).

[126]Plaintiffs' Opposition, Docket Entry No. 35, p. 22 (citing FACAC, Docket Entry No. 27, pp. 56-61 ¶¶ 162-73).

[127]Id.

(9th Cir. 2016), Sanders v. AVEO Pharmaceuticals, Inc., No. 13-11157-DJC, 2015 WL 1276824 (D. Mass. March 20, 2015), and Gerneth, 2018 WL 935418, plaintiffs argue that "differences of opinion need to be disclosed."[128]

The FACAC's allegations that defendants misrepresented the benefits of sotagliflozin by "tout[ing] trial results showing decreases in Alc, incidence of hypoglycemia and patient weight, even though [d]efendants knew that those decreases were not necessarily meaningful" or "clinically significant,"[129] are based on comments and observations made at the FDA Advisory Committee Meeting held on January 17, 2019.[130] For example, plaintiffs allege that more than one Advisory Committee "member[] questioned the clinical relevance of the modest reduction in hemoglobin A1c (HcA1c) shown with sotagliflozin,"[131] and that "

> another [c]ommittee member noted, "[a]lthough some individuals may have had astounding weight losses, the average change would not let this drug be approvable for a reduction of body weight because it's not a 5% reduction in weight, and that decrease is not necessarily considered a strong benefit."[132]

---

[128]Id. at 23.

[129]Id. at 22 (citing FACAC, Docket Entry No. 27, pp. 56-61 ¶¶ 162-73).

[130]Id. at 23-24 (citing FACAC, Docket Entry No. 27, pp. 38-40 ¶¶ 112, 116-17, and 41-42 ¶¶ 120-24).

[131]FACAC, Docket Entry No. 27, p. 38 ¶ 112.

[132]Id. at 42 ¶ 124 (citing Advisory Committee Meeting (continued...)

The FACAC also alleges that

> the FDA highlighted that while Sanofi had focused on the inTandem1 and inTandem2 studies to show reductions in incidences of severe hypoglycemia, "the trend went **in the opposite direction** for [inTandem 3]." . . . In sum, "there was **no consistent trend for hypoglycemia** across the three phase 3 studies.[133]

Missing from the FACAC, however, are any allegations of fact capable of showing that defendants failed to fully disclose the primary endpoints, inaccurately reported that the inTandem1 and inTandem2 trials met their primary endpoints for A1c reduction, or failed to accurately report incidences of hypoglycemia and weight loss. Nor are there any allegations of fact showing that defendants withheld internal information about the study design, the trial results or interpretations, or disagreements with the FDA or anyone else about the study design, the trial results, or the interpretation of those results. In short, the FACAC does not contain any allegations of fact capable of showing that when defendants made the statements about A1c reduction, incidences of hypoglycemia, and weight loss that the FACAC alleges were misleading, defendants failed to disclose any existing and available contradictory information.

---

[132] (...continued)
Transcript, p. 307:4-16, Exhibit 8 to Defendants' Motion to Dismiss, Docket Entry No. 34-15, p. 308).

[133] Id. at 41 ¶ 120 (citing Advisory Committee Meeting Transcript, p. 170:17-22, Exhibit 8 to Defendants' Motion to Dismiss, Docket Entry No. 34-15, p. 171).

Plaintiffs' contention that the defendants misrepresented the benefits of sotagliflozin because the positive trial results they reported with respect to A1c reduction, hypoglycemia, and weight loss were not necessarily meaningful is countered both by contradictory comments made by members of the FDA Advisory Committee at the Advisory Committee Meeting,[134] and by the Committee's tie vote of "'eight to eight' on the question of whether the overall benefits of sotagliflozin outweighed the risks to support approval."[135] Moreover, plaintiffs' have failed either to allege any facts or to cite any authority in support of their contention that defendants had a duty to disclose that the trial results were "not necessarily meaningful" or "clinically significant" as those terms generally refer to subjective concepts not facts. See Lehmann v. Ohr Pharmaceutical Inc., No. 18-Civ-1284 (LAP), 2019 WL 4572765, * 4 (S.D.N.Y. September 20, 2019) ("'[C]linically meaningful' is legally meaningless. Even if the term did have content, Plaintiffs have certainly not established that their definition is the definition of the term. . . . Additionally, the term, as a matter of law, is not a statement of

---

[134]See e.g., Advisory Committee Meeting Transcript, pp. 299:21-300:20 (acknowledging statistical improvements and benefit in glycemic control and weight loss), and 302:1-5 ("I think that what we can say was that while there was significant decrease in A1c, there was not any significant increase in hypoglycemia . . . that is a positive advantage"), Exhibit 8 to Defendants' Motion to Dismiss, Docket Entry No. 34-15, pp. 300-01, 302-03).

[135]FACAC, Docket Entry No. 27, p. 43 ¶ 126.

fact, but is instead, puffery, much the term "success." . . . Meaningfulness, especially in the medical context, is a more subjective concept than is the presentation of raw data.").

While McNamara, 197 F. Supp. 2d at 686-87, stands for the principle that defendants were required to disclose all facts necessary to make their statements not misleading, the FACAC's allegations that the defendants' statements about A1c reduction, incidences of hypoglycemia, and weight loss were actionably misleading represent an attack on the underlying methodology of the trials and the conclusions to be drawn from the results, not on the material falsity of defendants' statements about the benefits of sotagliflozin with respect to A1c reduction, hypoglycemia, or weight loss. See Abrams, 292 F.3d at 433 (quoting Novak, 216 F.3d at 309 ("As long as public statements are consistent with reasonably available data, corporate officials need not present an overly gloomy or cautious picture of the company's current performance or future prospects."). See also Nathenson, 267 F.3d at 420 (the securities laws do not require a company to disclose alleged inadequacies or shortcomings of clinical trials, as long as the trials are accurately described and the data is not falsified). The cases plaintiffs cite in support of their theory that defendants' statements regarding the benefits of sotagliflozin with respect to A1c reduction, hypoglycemia, and weight loss were actionably misleading bolster the court's conclusion that plaintiffs have failed to allege actionable omissions with respect to these issues.

In Schueneman the defendant, who like Lexicon was a bio-pharmaceutical company testing and developing new drugs, told investors that based on testing data including "all the animal studies that have been completed," the company was "confident" the drug would be approved. 840 F.3d at 702. Plaintiffs alleged that the company made that statement despite knowing and reporting to the FDA the result of an animal study that indicated the drug was causing tumors and various types of cancer in rats. Id. at 701. The Ninth Circuit held that while the company "may not have had a duty to disclose the Rat Study had they not been representing that animal studies supported [the drug]'s safety and therefore its likelihood of being approved . . . [but that] once [the company] chose to tout [the drug]'s likely approval by referencing allegedly positive animal and preclinical studies, they were bound to do so in a manner that wouldn't mislead investors." Id. at 707-708. Unlike Schueneman in which the plaintiffs alleged that the company made an affirmative statement that was misleading without the alleged omission, i.e., that animal studies made the company confident the drug would be approved, but failed to disclose the contradictory fact that an animal study showed the drug caused cancer in rats, the FACAC does not allege that Lexicon made any affirmative statements about A1c reduction, hypoglycemia, or weight loss but failed to disclose available, but contradictory facts.

Sanders, 2015 Wl 1276824, at *6, similarly demonstrates that courts have held statements about a drug's efficacy to be actionable when those statements are made in support of assertions that regulatory approval is "a when not if proposition," and the defendants fail to disclose subjective scientific disagreement over the drug's efficacy. Although the FACAC alleges that the FDA raised concerns with defendants about the utility of the composite endpoint, for the reasons stated in § II.B.1(a)(1), above, the court has already concluded that the FACAC fails to allege facts that are sufficiently particularized to make the failure to disclose an FDA concern about the composite endpoint actionable. Moreover, for the reasons stated in § II.B.1(a)(2), above, the court has already concluded that the FACAC fails to allege facts that are sufficiently particularized to make defendants' alleged DKA-related misrepresentations actionable. The FACAC's allegations regarding defendants' allegedly misleading statements about the benefits of sotagliflozin are comparable to the FACAC's allegations regarding FDA concern about the composite endpoint and defendants' statements about incidences of DKA that occurred during the phase 3 trials that the court has already found to be insufficient to state actionable omissions.

In each of the cases on which plaintiffs rely the allegations were found sufficient to allege actionable omissions because plaintiffs pleaded facts showing that when the defendants made

their allegedly misleading statements, those statements were directly contradicted by available but undisclosed information. Because the FACAC contains no comparable allegations of fact with respect to defendants' allegedly misleading statements about A1c reduction, hypoglycemia, and weight loss, the court concludes that plaintiffs have failed to plead facts sufficient to show that the alleged statements were misleading when the defendants made them.

(4) Plaintiffs' Allegations that Defendants Failed to Fully Disclose that Time-in-Range Was Not a Validated Endpoint Are Not Actionable

The FACAC alleges that the defendants misleadingly emphasized how sotagliflozin performed in relation to certain "glucose-based endpoints," including time-in-range and glycemic variability, without disclosing that these are not validated endpoints on eight different occasions, i.e., in Lexicon's 2015 and 2017 Annual Reports filed on Form 10-Ks with the SEC in March of 2016 and 2018; two earnings calls held on August 4, 2016, and November 8, 2017; two press releases issued on September 8, 2017, and June 23, 2018, and at two healthcare conferences held on September 5, 2018, and January 9, 2019.[136] The FACAC alleges that

> Defendants touted Sotagliflozin's performance in Phase 2 and Phase 3 clinical trials by emphasizing how the drug performed in relation to certain "glucose-based endpoints," including Time-in-Range and Glycemic Variability. As the FDA wrote in its briefing materials,

---

[136]Id. at 61-63 ¶¶ 174-82.

> however, "[w]hile these endpoints, [i.e., Time-in-Range and Glycemic Variability] are valued by patients and may relate to at least short-term improvements in quality of life and treatment satisfaction, these **do not have an established relationship with long-term macrovascular and microvascular complications** and **have not been validated for use in regulatory decision making for antidiabetic drugs."** In other words, sotagliflozin's performance with regard to Time-in-Range and Glycemic Variability was entirely irrelevant as to whether the Advisory Committee recommended that the FDA approve sotagliflozin or whether the FDA ultimately approved the drug.[137]

The FACAC alleges that defendants' statements about time-in-range and glycemic variability

> referenced in ¶¶ 174-181 were materially false and misleading because . . . Defendants failed to disclose that those measures did not have an established relationship with long-term macrovascular and microvascular complications and were not [] validated for use in regulatory decision making, and thus would have no impact on whether the Advisory Committee recommended sotagliflozin or the FDA ultimately approved the drug.").[138]

Defendants argue that the FACAC's allegations they misrepresented the validity of time-in-range and glycemic variability should be dismissed because "Lexicon told investors this precise information in their second quarter 2017 earnings call on August 1, 2017."[139]

---

[137]Id. at 61-62 ¶ 174.

[138]Id. at 63 ¶ 182.

[139]Defendants' Motion to Dismiss, Docket Entry No. 33, p. 24. See also Defendants' Reply, Docket Entry No. 37, p. 20.

Plaintiffs respond that

> [d]efendants told investors that Glycemic Variability benefitted patients. ¶ 176. They also told investors that the inTandem2 trial showed "improvements in certain elements of glycemic control" including "glycemic variability." ¶ 180. But [d]efendants never disclosed that Glycemic Variability was entirely irrelevant to the Committee and the FDA's consideration of sotagliflozin. Since [d]efendants never disclosed that Glycemic Variability was not a validated endpoint, the Motion as to these misstatements should be denied.[140]

Defendants reliance on the text of Lexicon's second quarter earnings call on August 1, 2017, to counter the FACAC's allegations that their statements about time-in-range and glycemic variability were misleading by showing that Lexicon did, in fact, disclose that these were not validated endpoints is misplaced because the FACAC neither references nor incorporates the earnings call held on August 1, 2017. Because defendants do not argue, and the court does not find, that the text of the August 1, 2017, earnings call is subject to judicial notice, the court cannot consider the text of that call in ruling of the pending motion to dismiss without converting the motion to one for summary judgment. See Dorsey, 540 F.3d at 338 (quoting Tellabs, 127 S. Ct. at 2509) (courts may "rely on 'documents incorporated into the complaint by reference, and matters of which a court may take judicial notice'"). See also Wehlmann, 737 F. Supp. 2d at 616 (courts may consider "the full text of documents partially quoted in the complaint").

---

[140]Plaintiffs' Opposition, Docket Entry No. 35, p. 24 (citing FACAC, Docket Entry No. 27, pp. 56-61 ¶¶ 174-81).

The FACAC acknowledges that Lexicon disclosed primary, secondary, and composite endpoints of the phase 3 trials, and that "[s]otagliflozin . . . achieved the endpoints [d]efendants . . . designed."[141] The FACAC does not allege that defendants identified time-in-range or glycemic variability as endpoints for the phase 3 studies, stated that time-in-range or glycemic variability were validated for regulatory decision making, or that the defendants' statements about time-in-range or glycemic variability were made in support of assertions that the Advisory Committee would recommend sotagliflozin for approval or that the FDA would approve the NDA for sotagliflozin. Nor does the FACAC contain any allegations of fact showing that when defendants made statements about time-in-range or glycemic variability alleged to be misleading, they failed to disclose existing and available contradictory information, including e.g., that sotagliflozin's performance with respect to these measures would be entirely irrelevant to either the Advisory Committee or the FDA. Moreover, plaintiffs' contention that the defendants' statements about time-in-range and glycemic variability were misleading because they failed to disclose that these measures were irrelevant to the Advisory Committee and to the FDA is contradicted by the transcript of the Advisory Committee Meeting.[142]

---

[141]FACAC, Docket Entry No. 27, p. 75 ¶ 218.

[142]Because the transcript of the Advisory Committee Meeting is partially quoted by and incorporated into the FACAC, the court may (continued...)

The transcript of the Advisory Committee meeting shows that time-in-range and glycemic variability were not only addressed by committee members and public speakers, but also discussed and considered by committee members while deciding whether sotagliflozin's benefits outweighed its risks. For example, following the formal presentations made by the sponsor, Sanofi, and by the FDA, one committee member stated that she wanted

> to congratulate both the agency and the sponsor for the robust sets of date . . . presented. It's encouraging to see the use [of] real-world evidence as well as other measures beyond A1C, so thank you for that.
>
> I was particularly interested in the time in range. While some of us are skeptical about the benefit of measuring A1c or what the clinical relevance is, even though we understand it, I was wondering if you took any further analysis of the time in range data to look to see if there was glycemic variability or decreases in glycemic variability, and things like postprandial glucose levels.[143]

In addition, public speakers pointed out the importance of time-in-range and glycemic variability to patients. For example a T1d patient stated that

> [y]ou have heard the phrase "time in range" today, and hopefully you continue to hear this term more and more in clinical trials. To someone living with diabetes, time in range is not just a term or a goal. It represents

---

[142](...continued)
consider it in ruling on Defendants' Motion to Dismiss. See Dorsey, 540 F.3d at 338 (quoting Tellabs, 127 S. Ct. at 2509). See also Wehlmann, 737 F. Supp. 2d at 616 (courts may consider "the full text of documents partially quoted in the complaint").

[143]Advisory Committee Meeting Transcript, pp. 194:12-195:2, Exhibit 8 to Defendants' Motion to Dismiss, pp. 195-96.

> when you can live your life. It means being able to concentrate, having energy to play with your kids, and being productive at work.[144]

Another patient commented that

> [y]ou've heard everyone talk about time in range. I do think it relates to the A1c to some degree. When you have less highs and less lows, it's not only a quality-of-life issue, but there is data now to indicate that it may reduce microvascular complications.
>
> That's why patients want this drug. They will seek out this drug, whether sotagliflozin is approved or not. And that's why I think we need regulation and we need education. And I can tell you the burden is living with type 1 diabetes, not testing the glucose or ketone levels.
>
> So I say let the patient, and myself included, have a say in the risk-benefit ratio.[145]

During the committee's discussion of sotagliflozin's benefits a committee member who eventually voted "no" to the question of whether sotagliflozin's benefits outweighed its risks, nevertheless recognized the importance of time-in-range and glycemic variability by stating that

> even though this degree of A1c lowering is modest, 0.3 to 0.4 percent, I think that glycemic variability and time in range is important. I have plenty of patients with type 1 in my practice who have been struggling so much to try to get A1cs down, but it's the hypoglycemia that limits things.
>
> So I think the descriptions of how well the drug has worked from the open public hearing, [are] really compelling, but that doesn't alleviate my concerns about the drug. But I do want to say that I think that the

[144]Id. at 237:10-17, Docket Entry No. 34-15, p. 238.

[145]Id. at 286:18-287:9, Docket Entry No. 34-15, pp. 287-88.

> A1c, just the modest degree of A1c lowering, doesn't capture the whole thing. I think glycemic variability is pretty important.[146]

Summarizing the committee's discussion of sotagliflozin's benefits, the Committee Chairman stated, "In general, the endocrinologists were encouraging us to think beyond A1c, . . . mentioning very good time in control and the appropriate ranges of control."[147]

During the committee's discussion of sotagliflozin's risks a committee member raised the need to look beyond A1c by stating that

> . . . [t]here's a recognition of the agency, and now in the research community, and certainly in the patient community, of the inadequacy of A1c as a measure for living with a disease for the rest of your life, day in, day out.
>
> In terms of the impact of glucose variability on life and functionality, it is significant. If you get hypoglycemia, particularly severe hypoglycemia, or even if it's not that severe but you've got a substantial drop that's very volatile, the impact on your ability to think is drastic, and it can happen for days.[148]

That same committee member addressed the need for better validated measures by stating that

> . . . the issue is we need better validated measures that look at glycemic variability and the impact of glycemic variability on quality of life, functionality, cognitive functioning, et cetera. But those aren't there yet,

[146]Id. at 304:2-15, Docket Entry No. 34-15, p. 305 (comments from Dr. Cecelia Low Wang). See also id. at 373:1-376:21, Docket Entry No. 34-15, pp. 374-76 (Dr. Low Wang stated reasons for her "no" vote).

[147]Id. at 305:6-7, 12-15, Docket Entry No. 34-15, p. 306.

[148]Id. at 319:22-320:11, Docket Entry No. 34-15, pp. 320-21.

> necessarily. They presented two quality-of-life measures among patient-reported outcomes.
>
> Whether or not they're good or not, they're validated. That's what they had, and they presented some on time in range, which I think is significant and important, but we need better measures. But we don't have them at this point, so the sponsor shouldn't necessarily be held to a standard to be providing that data beyond what they've already done just because that's not where the regulatory process is.[149]

In summing up the discussion of sotagliflozin's risks, the Committee Chairman stated, "DKA is one metric. Time in range is another. And we need to figure out how to put this all together in some way to take care of patients."[150]

In summing up the discussion of the overall risk-benefit profile of sotagliflozin, the committee chairman stated that

> . . . as we've been discussing this, I have the benefits, I have the negatives, I have the nulls, and then I have potentially other metrics.
>
> On the benefit side, we have A1c, time in range, weight, blood pressure. Unanswered are micro- and macrovascular disease. On the adverse, we have DKA . . . For the null, we have hypoglycemic risk.
>
> Then we're lacking integrative metrics. We need a diabetes integrated metric. That might be part of what we would recommend moving forward, is to develop this, because we don't have it.[151]

The transcript of the Advisory Committee Meeting shows that time-in-range and glycemic variability were not only discussed, but

---

[149]Id. at 321:2-18, Docket Entry No. 34-15, p. 322.

[150]Id. at 322:22-323:3, Docket Entry No. 34-15, pp. 323-24.

[151]Id. at 347:22-348:13, Docket Entry No. 34-15, pp. 348-49.

also considered by committee members when deciding whether sotagliflozin's benefits outweighed its risks. The court concludes, therefore, that neither defendants' statements about time-in-range and glycemic variability nor defendants' failure to disclose either that time-in-range and glycemic variability were not validated endpoints or that time-in-range and glycemic variability were "entirely irrelevant to the Committee and the FDA's consideration of sotagliflozin," are actionable.

(5) Plaintiffs' Allegations that Defendants Mislead Investors About Their Risk Management Protocol Are Not Actionable

The FACAC alleges defendants misrepresented the effectiveness of Lexicon's risk management plan on five different occasions, i.e., in one earnings call held on November 8, 2017; two press releases issued on June 23 and 24, 2018; and in two presentations made by defendant Coats at healthcare conferences held on January 11, 2017, and January 9, 2019.[152] Plaintiffs allege that

> Defendants . . . made materially false and/or misleading statements throughout the Class Period by telling investors that they were developing or had developed an effective risk management program to address DKA, but failing to disclose that they had utterly failed to create any semblance of such a plan. These misrepresentations were material because Defendants knew that they needed to propose a risk management program given the increase in incidence of DKA and the FDA's prior statements of concern about DKA associated with SGLT-2 inhibitors, like sotagliflozin.[153]

---

[152]FACAC, Docket Entry No. 27, pp. 64-66 ¶¶ 183-91.

[153]Id. at 64 ¶ 183. See also id. at 65 ¶ 187 ("Defendants (continued...)

Citing a large number of documents not referenced in the FACAC, defendants respond that plaintiffs' allegations that they "failed to disclose that Lexicon did not have a meaningful risk management plan for DKA," should be dismissed because (1) Lexicon accurately disclosed the limitations of its DKA risk management protocol and that it would be a key issue for FDA approval on multiple occasions throughout the class period,[154] and (2) "analysts commented on the feasibility of the clinical risk management plan in the 'real world' and noted that FDA review would focus on DKA risk management."[155] Citing the transcript from the Advisory Committee Meeting, defendants argue that "the debate at the Advisory Committee centered not only on the feasibility of Lexicon's risk management plan, but on the feasibility of any risk management plan to adequately address the DKA risk,"[156] and that

---

[153](...continued) repeatedly represented to investors that they understood the need for a risk management plan and were in fact developing such a plan, but failed to disclose that no such plan existed."); and 66 ¶ 191 (Defendants . . . represented to investors that [they] understood the need for a thorough, detailed and demonstrably effective risk management plan and were in fact developing such a plan. These statements were materially misleading, however, because [defendants] failed to disclose to investors that no such plan existed.).

[154]Defendants' Motion to Dismiss, Docket Entry No. 33, pp. 25-27. See also Defendants' Reply, Docket Entry No. 37, p. 17 (arguing that "[p]laintiffs do not allege that Lexicon held back some internal information about its study design, including the DKA incidence and the risk management plan. . .").

[155]Defendants' Motion to Dismiss, Docket Entry No. 33, p. 26.

[156]Id. (citing Advisory Committee Meeting Transcript, Exhibit 8 to Defendants' Motion to Dismiss, pp. 362:17-364:3, 369:15-20, (continued...)

"[p]laintiffs cannot claim credibly that they were unaware of the state of the science; the need for an industry-standard DKA risk management protocol was well-known to investors."[157]

Asserting that "[d]efendants ask the [c]ourt to take judicial notice of fifteen documents that are neither attached to nor referenced in the FAC[AC],"[158] plaintiffs argue that the court should not consider the documents on which defendants rely because they are irrelevant and because "they either say nothing about the risk management plan [d]efendants would present to the FDA or merely reiterate that a DKA risk management plan was essential to FDA approval . . . of sotagliflozin."[159] Asserting that "[d]efendants point to their own self-serving statements at the [Advisory Committee] Meeting [as] suggesting that their risk management protocol was effective in reducing DKA,"[160] plaintiffs argue that "when the FDA informed the Committee during the Q&A portion of the meeting that 'there's no difference in the rate of [DKA] before and after' risk management measures were implemented (¶ 125), Lexicon's own experts acknowledged that this was true."[161]

---

[156](...continued)
Docket Entry No. 34-15, pp. 363-64, and 370).

[157]Id.

[158]Plaintiffs' Opposition, Docket Entry No. 35, p. 26.

[159]Id.

[160]Id. n. 10.

[161]Id. (citing Advisory Committee Meeting Transcript, p. 290:3-15, Exhibit 8 to Defendants' Motion to Dismiss, Docket Entry (continued...)

Defendants' reliance on documents that are neither referenced nor incorporated into the FACAC in support of their Motion to Dismiss is misplaced because defendants do not argue, and the court does not find, that the cited documents are subject to judicial notice, and the court may not consider them without converting the motion to one for summary judgment. Fed. R. Civ. P. 12(d). See Dorsey, 540 F.3d at 338 (quoting Tellabs, 127 S. Ct. at 2509 (courts may "rely on 'documents incorporated into the complaint by reference, and matters of which a court may take judicial notice'"). Nevertheless, the court concludes that plaintiffs' allegations that defendants made statements about a DKA risk management plan that were materially misleading because defendants told "investors that they were developing or had developed an effective risk management program to address DKA, but fail[ed] to disclose that they had utterly failed to create any semblance of such a plan,"[162] are not actionable because they are contradicted by the transcript of the Advisory Committee Meeting that is referenced multiple times in the FACAC and which the court may consider without converting defendants' motion to a motion for summary judgment. See Dorsey, 540 F.3d at 338 (quoting Tellabs, 127 S. Ct. at 2509). See also Wehlmann, 737 F. Supp. 2d at 616 (recognizing

---

[161](...continued)
No. 34-15, p. 291).

[162]FACAC, Docket Entry No. 127, p. 64 ¶ 183.

that courts may consider on motions to dismiss "the full text of documents partially quoted in the complaint"). The FACAC's allegations regarding a DKA risk management plan are contradicted by the Advisory Committee Meeting transcript, which shows that a DKA risk management plan existed, and that the Advisory Committee discussed and considered the plan. See United States ex. rel. Riley v. St. Luke's Episcopal Hospital, 355 F.3d 370, 377 (5th Cir. 2004)("If . . . an allegation is contradicted by the contents of an exhibit attached to the pleading, then . . . the exhibit and not the allegation controls.").

Sanofi's presentation to the Advisory Committee included a slide titled, "Proposed Risk Management Program to Reduce Risk of DKA" that stated:

- Based on current practice guidelines
  - Patient selection, ketone monitoring, insulin management, recognizing at-risk situations, and use of sick-day rules
- Communication risk of DKA to HCPs and patients
  - Educational materials and patient leaflets.[163]

Plaintiffs argue that "when the FDA informed the Committee during the Q&A portion of the meeting that 'there's no difference in the rate of [DKA] before and after' risk management measures were implemented (¶ 125), Lexicon's own experts acknowledged that this

---

[163]Exhibit 7 to Defendants' Motion to Dismiss, Docket Entry No. 34-14, p. 12.

was true."[164] But what Lexicon's expert actually acknowledged was that "the studies were not assigned [sic.] to make an assessment between the two[, i.e., the rate of DKA before and after risk management measures were implemented]."[165] The transcript of the Advisory Committee Meeting also shows that the efficacy of the DKA risk management plan was not one of the issues the committee was asked to consider, but that the committee members nevertheless considered the DKA risk management plan when voting on their fifth and final question: "Whether sotagliflozin's benefits outweighed it risks and should be recommended for approval."[166] Although the

---

[164]Plaintiffs' Opposition, Docket Entry No. 35, p. 26 & n. 10 (citing Advisory Committee Meeting Transcript, p. 290:3-15, Exhibit 8 to Defendants' Motion to Dismiss, Docket Entry No. 34-15, p. 291).

[165]Id. 290:13-14, Docket Entry No. 34-15, p. 291. See also id. at 333:16-19, Docket Entry No. 34-15, p. 334 (committee member observing that "the risk mitigation strategy put forth by the sponsor in the presentations that really hasn't been tested in the trials is something that a lot of people are thinking about"); id. at 338:6-8, Docket Entry No. 34-15, p. 339 (FDA representative stating that "the ketone monitoring, as the sponsor pointed out, was introduced on April 1, 2016. And the sponsor also pointed out that patients might have been randomized at different dates. . . [but] the hazard ratio . . . [was] about the same . . . before and after, April 1, 2016").

[166]Id. at 354:2-16, Docket Entry No. 34-15, p. 355.

> DR. WILSON: Okay. Then the other question, at least for some of the committee, it has come up, and it certainly has come up for me, personally, there has been a proposed REMS [Risk Evaluation and Mitigation Strategy] or a mitigation strategy by the sponsor.
>
> When and where might we discuss that topic? Should

(continued...)

committee members disagreed about whether a DKA risk management plan was needed before sotagliflozin could be approved,[167] almost all of the committee members expressed not only a need for a DKA risk management plan but also a desire for testing to show that a risk management plan would be effective.[168]

Because the transcript of the Advisory Committee Meeting shows that contrary to the allegations in the FACAC, Lexicon had a DKA risk management plan that was not tested during the phase 3 trials, and because the FACAC contains no allegations that defendants falsely described the contents of those trials as including a risk management plan, that defendants possessed undisclosed information showing that their risk management plan would not be effective, or that defendants did not believe that it would be effective, the court concludes that defendants' statements that they "were

---

[166] (...continued)
we vote and then discuss it, or should be discuss what a REMS project might be in advance? Just provide us some advice on that.

DR. YANOFF: I believe that's a question that could fit into the explanation via our recommendation exactly.

DR. WILSON: That could probably be 5B, so we'll put it there, with 5B? So we'll hold off until we vote, and then we'll discuss.

[167] See id. at 369: 2-6 (Committee Chairman states, "do you need the REMS before you approve or could you do a REMS as you approve? That's, I think, one of the toughest parts of this whole process, is we'd like to see something in place that would show benefit and less DKA.").

[168] Id. at 357:2-382:15, Docket Entry No. 34-15, pp. 358-83.

developing or had developed an effective risk management plan were not misleading," and that defendants' failures to disclose that they had no semblance of such a plan are not actionable omissions. See Nathenson, 267 F.3d at 420 (the securities laws do not require a company to disclose alleged inadequacies or shortcomings of clinical trials, as long as the trials are accurately described and the data is not falsified). The fact that virtually all members of the Advisory Committee expressed concern about the effectiveness of the risk management plan presented at the Advisory Committee Meeting does make defendants' statements about the risk management plan fraudulent. See In re AstraZeneca Securities Litigation, 559 F. Supp. 2d 453, 471 (S.D.N.Y. 2008), aff'd, 334 F. App'x 404 (2d Cir. 2009) (nearly unanimous vote of FDA Advisory Committee not to recommend a drug for approval did not mean that information issued publicly by the sponsor was dishonest or recklessly disseminated").

(6) Conclusions

For the reasons stated above the court concludes that neither the materials presented, the comments made, nor the tie vote on the question of whether the benefits of sotagliflozin outweigh its risks taken at the Advisory Committee Meeting held on January 17, 2019, support plaintiffs' claims that defendants misrepresented the results of the phase 3 trials by (1) failing to disclose FDA warnings against the composite endpoint, (2) misrepresenting the

extent and severity of DKA, (3) misrepresenting the benefits of sotagliflozin, (4) failing to fully disclose that "time-in-range" was not a validated endpoint, and (5) misleading investors about their risk management protocol.

Plaintiffs' reliance on materials presented, comments made, and the vote taken at the Advisory Committee Meeting in support of their allegations that defendants committed securities fraud is analogous to allegations of fraud by hindsight, i.e., where a plaintiff alleges the fact that a company reports negative results means that the company's prior reports of good results must have been false or misleading. The Fifth Circuit has made clear, however, that allegations of negative results are generally not sufficient to satisfy the requirements for pleading securities fraud, and that plaintiffs must allege facts capable of raising a plausible inference that earlier statements were false when made. The court concludes that the FACAC is subject to dismissal for failure to allege an actionable misrepresentation because the FACAC's allegations of defendants' omissions do not contain facts capable of establishing that any of the alleged omissions caused any of defendants' statements to be false or misleading when made. As another district court has recently observed in ruling on a motion to dismiss involving similar albeit not identical facts,

> were plaintiffs' version of falsity the law, a pharmaceutical company could be sued for securities fraud each and every time it received a NDA rejection from the FDA. Potential plaintiffs could merely parrot any

> deficiency identified by the FDA . . . and then claim the company concealed from the market that it failed to include this "necessary" piece of information in its application. Plaintiffs would further claim that the company knowingly concealed from the market the corresponding "exceedingly high risk" of FDA rejection. These same potential plaintiffs would then classify the company's decision to omit whatever, in hindsight, the FDA said was missing from the NDA as a "reckless gamble," and the inevitable decline in the stock price would be classified as a monetary loss caused by this material omission.

Immanuel Lake v. Zogenix, Inc., No. 19-cv-01975-RS, 2020 WL 3820424, at *9 (N.D. Cal. January 24, 2020). More is needed to plead actionable omissions under § 10(b) and Rule 10b-5, as the case law discussed above has made clear.

(b) Plaintiffs Fail to Plead Scienter

Defendants argue that they are entitled to dismissal of the § 10(b) and Rule 10b-5 claims asserted against them because plaintiffs failed to plead scienter.[169] Defendants argue that plaintiffs' pleadings fail to distinguish between them with respect to allegations of scienter, and that plaintiffs' scienter theory relies exclusively on assertions that would almost universally be true, such as the desires to raise capital and protect their compensation packages.[170] Asserting that if they

[169]Defendants' Motion to Dismiss, Docket Entry No. 33, pp. 27-29.

[170]Id. at 28.

> were engaged in a scheme to mislead investors and [the] FDA about the results of their clinical trials, then they would not have disclosed the[] precise results repeatedly and publicly. . . . [and] would not have warned repeatedly about the risk that [the] FDA would not approve its investigational drugs,[171]

defendants argue that "the more compelling inference is that [they] made a good faith effort to comply with all applicable disclosure and regulatory requirements — and that [they] believed that the benefits of sotagliflozin outweighed its risks."[172]

Plaintiffs respond that they have adequately pleaded scienter by alleging that the Individual Defendants (1) designed the Phase 3 trials to mask the incidence of DKA, (2) knew their statements were misleading because they were responsible for all clinical development activities, met with the FDA, and received data directly from trial investigators, (3) were motivated to misrepresent the trial results because their compensation was tied to the FDA's approval of sotagliflozin and Lexicon needed that approval to survive, and (4) their warnings that the FDA might not approve sotagliflozin were too generic to create an inference of non-fraudulent intent as compelling as the inference of scienter.[173]

---

[171]Id. at 29 (citing id. at 12-16).

[172]Id. See also Defendants' Reply, Docket Entry No. 37, pp. 7-10 (especially p. 8 citing In re AstraZeneca, 559 F. Supp. 2d at 458 and 471, and Oppenheim Primerica Asset Management S.A.R.L. v. Encysive Pharmaceuticals, Inc., No. H-06-3022, 2007 WL 2720074, *5 (S.D. Tex. September 18, 2007), in support of the argument that "[t]he more compelling inference is that [d]efendants honestly believed that the DKA risk could be effectively managed, and thus was outweighed by sotagliflozin's benefits").

[173]Plaintiff's Opposition, Docket Entry No. 35, pp. 27-30.

Plaintiffs argue that Coats and Lapuerta's scienter is shown by their statements that sotagliflozin's benefits outweighed its risks and that the Phase 3 trials showed only a "slight" increase in DKA.[174] Plaintiffs also argue that the Individual Defendants' positions within the company are sufficient to allege scienter pursuant to "special circumstances" recognized by the Fifth Circuit in Nathenson, 267 F.3d at 400, and Dorsey, 540 F.3d at 333.[175]

For the reasons stated in § II.B.1(a), above, the court has already concluded that this action is subject to dismissal because the FACAC fails to allege an actionable misrepresentation. The FACAC's failure to allege an actionable misrepresentation precludes plaintiffs from raising a strong inference of scienter with respect to any of the alleged misrepresentations. Alternatively, assuming that the alleged misrepresentations are actionable, the court concludes that this action is subject to dismissal because plaintiffs have not alleged facts supporting a strong inference that the alleged misrepresentations were made with scienter.

(1) Additional Law

The PSLRA, 15 U.S.C. § 78u-4(b)(2), requires plaintiffs to "state with particularity facts giving rise to a strong inference that the defendant[s] acted with the required state of mind." "The

[174] Id. at 28.

[175] Id. at 28-29.

required state of mind [for scienter] is an intent to deceive, manipulate, or defraud or severe recklessness." Lormand, 565 F.3d at 251 (quoting Indiana Electrical, 537 F.3d at 533). "Severe recklessness" is

> limited to those highly unreasonable omissions or misrepresentations that involve not merely simple or even inexcusable negligence, but an extreme departure from the standards of ordinary care, and that present a danger of misleading buyers or sellers which is either known to the defendant or is so obvious that the defendant must have been aware of it.

Indiana Electrical, 537 F.3d at 533 (citation omitted). In Tellabs, 127 S. Ct. at 2510, the Supreme Court held that a complaint will survive a motion to dismiss "only if a reasonable person would deem the inference of scienter cogent and at least as compelling as any opposing inference one could draw from the facts alleged." See also Spitzberg v. Houston American Energy Corp., 758 F.3d 676, 683-84 (5th Cir. 2014) (same); and Lormand, 565 F.3d at 251 ("[I]n determining whether the pleaded facts give rise to a 'strong' inference of scienter, the court must take into account plausible opposing inferences."). The critical issue in a motion to dismiss for failure to allege scienter "is whether all of the facts alleged, taken collectively, give rise to a strong inference of scienter, not whether any individual allegation, scrutinized in isolation, meets that standard." Tellabs, 127 S. Ct. at 2509. See also Barrie v. Intervoice-Brite, Inc., 397 F.3d 249, 259 (5th Cir. 2005) (acknowledging that courts "consider all the facts and circumstances alleged to determine whether they, in toto, raise a requisite strong inference of scienter").

Plaintiffs "must allege facts sufficient to raise a strong inference of scienter with respect to each individual defendant." R2 Investments LDC v. Phillips, 401 F.3d 638, 643 (5th Cir. 2005) See Southland, 365 F.3d at 365 ("[T]he PSLRA requires the plaintiffs to distinguish among those they sue and enlighten each defendant as to his or her particular part in the alleged fraud."). Group allegations that "the defendants" or "the company" knew something do not meet that standard. Indiana Electrical, 537 F.3d at 533 ("[T]his court has rejected the group pleading approach to scienter and instead looks to the state of mind of the individual corporate official or officials 'who make or issue the statement (or order or approve it or its making or issuance, or who furnish information or language for inclusion therein, or the like) rather than generally to the collective knowledge of all the corporation's officers and employees acquired in the course of their employment.'")(quoting Southland, 365 F.3d at 366)).

In the context of the development of a new drug, "[i]f the management knows that certain facts will necessarily prevent the regulatory approval . . . and conceals these facts from the investing public, then there is scienter." In re AstraZeneca, 559 F. Supp. 2d at 470. Scienter also exists "if the management is reckless in dealing with such adverse facts." Id. If, however, management releases positive reports about a drug to the public that management honestly believes to be true, and there is no reckless disregard for the truth, then there is no scienter. Id.

(2) Analysis

(i) Defendants' Trial Design and Statements Do Not Strongly Infer Scienter

The FACAC alleges that

> [d]efendants had actual knowledge that the statements they were making about the performance of sotagliflozin in the Phase 3 Trials were misleading because Lexicon was responsible for the clinical development of sotagliflozin for T1d under the Sanofi Agreement, had met with FDA officials and had received data directly from the investigators conducting the trials, the development of sotagliflozin was essential for Lexicon's survival, and [d]efendants had designed the Phase 3 Trials to conceal the increased risk of DKA.
>
> In addition, confidential witnesses who worked for [d]efendants corroborated [d]efendants' knowledge of the problems with sotagliflozin in the Phase 3 Trials. CW1, for example, was the receptionist at Lexicon's headquarters in The Woodlands, Texas, from July 2015 to February 2018. Although CW1 was the receptionist, she performed work for all of Lexicon's departments. CW1 participated in the submission of sotagliflozin to the FDA because she (i) attended at least two mock presentations in the second half of 2017 at Lexicon that were trial runs of what [d]efendants and Sanofi would present to the FDA regarding the forthcoming NDA for sotagliflozin, and (ii) performed research on DKA and hypoglycemia for [d]efendants and other Lexicon and Sanofi employees to use in addressing the FDA's concerns about those conditions. CW1 described how she received explicit, detailed instructions on what she could and could not say about sotagliflozin to individuals entering or leaving Lexicon's headquarters. Lexicon required CW1 to practice her responses to questions from hypothetical individuals entering or leaving Lexicon's headquarters.
>
> CW1 said that the mock presentations indicated that there were problems with sotagliflozin. Executives at Lexicon stormed out of the presentations screaming, "[t]he research isn't there. This is going to hell!" CW1 also recalled that members of Lexicon's research department told her that sotagliflozin "is going to be tough. This one is going to be harder to get through."

> They said that, "XERMELO was easy, sotagliflozin is going to be hard."
>
> Similarly, CW2 was a Vice-President for Sales at Lexicon from 2016 to 2017. CW2 participated in a quarterly call in 2017, in which sotagliflozin was discussed with representatives of the European Association for the Study of Diabetes. CW2 said that incidences of DKA in the Phase 3 Trials were discussed on the call, and that he believed Lexicon [w]as "spinning" the incidences of DKA, including by highlighting how the setting of the Phase 3 Trials could have contributed to the incidence of DKA.[176]

Missing from the FACAC are allegations of specific facts connecting any of the Individual Defendants to the vast majority of the alleged misrepresentations. Neither the facts alleged in the FACAC nor the accounts of the confidential witnesses demonstrate that any of the Individual Defendants made any conscious misrepresentation concerning the performance of sotagliflozin in the phase 3 trials or the design of those trials.

Plaintiffs' allegations that defendants designed the phase 3 trials to conceal the increased risk of DKA are conclusory and unsupported by facts capable of establishing that the trials were designed by any of the named defendants or designed to highlight the benefits of sotagliflozin while concealing the risks of DKA. As discussed in § II.B.1(a)(2), above, these allegations are based solely on comments made by the FDA and members of the advisory committee at the Advisory Committee Meeting held on January 17, 2019, long after almost all of the alleged misrepresentations were

[176]FACAC, Docket Entry No. 27, pp. 33-34 ¶¶ 96-99.

made. Nor are there allegations of fact capable of establishing that defendants withheld internal information about the study design, the trial results or interpretations, or disagreements with the FDA or anyone else about the study design, the trial results, or their interpretation. In short, the FACAC does not contain any allegations of fact showing that when defendants made the statements alleged to be misleading, defendants were aware of contradictory information that they failed to disclose.

Also missing from the FACAC are allegations of fact showing when or where defendants met with the FDA or what was discussed at those meetings, when defendants received data from investigators conducting the trials or what data they received, or why that data contradicted any of defendants' alleged misrepresentations.

Nor are there any allegations of fact showing that the development of sotagliflozin was essential for Lexicon's survival. The Annual Reports cited in the FACAC all show that sotagliflozin was neither Lexicon's only product nor its only potentially profitable product. For example, the FACAC alleges that

> [a]t the start of the Class Period, on March 11, 2016, Lexicon filed its annual report on Form 10-K for the year 2015, which was signed by the Individual Defendants (the "2015 10-K"). That report disclosed, among other things, that Lexicon was "presently devoting most of our resources to the development of our two most advanced drug candidates." These drugs were "XERMELO," an oral treatment for carcinoid syndrome diarrhea, and sotagliflozin.[177]

[177]Id. at 16 ¶ 50.

Moreover, Lexicon's Annual Report for 2016 stated that "[w]e have obtained approval from the . . . FDA to sell our first commercial product, XERMELO,"[178] and Lexicon's Annual Report for 2017 stated that "[w]e commercially launched XERMELO . . . following regulatory approval in the United States in February 2017 . . . ."[179] Thus, factual allegations contained in the FACAC, and facts stated in Lexicon's Annual Reports for 2016 and 2017, both of which are referenced by and incorporated into the FACAC, counter plaintiffs' contention that sotagliflozin was essential for Lexicon's survival.

The FACAC's allegations of information received from CW1 and CW2 are not sufficient to raise any inference — much less a strong inference — of scienter. Neither the fact that CW1 was coached on what to say about sotagliflozin to individuals visiting Lexicon's headquarters, nor her accounts of mock presentations at which unnamed executives exclaimed "[t]he research isn't there. This is going to hell!," or of conversations with members of Lexicon's research department who said that sotagliflozin "is going to be tough," show that any of defendants' alleged misrepresentations were false, misleading, or made with scienter.

CW2's report that he believed Lexicon was "spinning" the incidences of DKA during a conference call held in 2017 that is not

[178] 2016 Annual Report, Form 10-K, p. 1, Exhibit 3 to Defendants' Motion to Dismiss, Docket Entry No. 34-3, p. 4.

[179] 2017 Annual Report, Form 10-K, p. 2, Exhibit 4 to Defendants' Motion to Dismiss, Docket Entry No. 34-4, p. 5.

otherwise alleged in the FACAC similarly fails to raise any inference of scienter because CW2 neither describes what was said to make him think that Lexicon was "spinning" the incidences of DKA, nor explains why the setting of the phase 3 trials could have contributed to the incidence of DKA. Fatal to plaintiffs' arguments regarding the confidential witness accounts is that the FACAC fails to allege that either CW1 or CW2 presented information to or about any Individual Defendant capable of establishing that any of the representations alleged to be false or misleading was, in fact, inaccurate or known by any of the defendants to have been inaccurate. See In re Citigroup Inc. Securities Litigation, 753 F.Supp.2d 206, 245 (S.D.N.Y. 2010) ("Plaintiffs cannot rely on assertions that the information presented by confidential witnesses was known or common knowledge within the company; these assertions are too vague and conclusory to support a finding that defendants knew they were making false statements or made those statements with reckless disregard for their truth or falsity.").

Plaintiffs argue that "Coats and Lapuerta's scienter is shown by their statements placating analysts and/or at conferences about how they had structured Phase 3 Trials to prove that [] sotagliflozin's benefits outweighed its risks and that the trials showed only a 'slight' increase in DKA."[180] But even assuming that

[180]Plaintiffs' Opposition, Docket Entry No. 35, pp. 28 (citing FACAC, Docket Entry No. 27, pp. 25 ¶ 77, 47-48 ¶¶ 140-41, 49-50 ¶ 144, 52-53 ¶¶ 150-51, 62-63 ¶¶ 177-78).

these statements were misleading, plaintiffs fail to allege facts showing that Coats and Lapuerta had ample reason to know that their statements were false or misleading. Absent particularized allegations capable of showing that Coats and Lapuerta had ample reason to know the falsity of their statements, false statements alone are not sufficient to raise a strong inference of scienter.

(ii) Defendants' Motivations

Nor have plaintiffs alleged facts capable of raising a strong inference of scienter with respect to the defendants' alleged motivations for making the alleged misrepresentations. In support of this argument plaintiffs cite the FACAC's allegations that

> the Individual Defendants' scienter is also established because the alleged misstatements and omissions at issue here concerned Lexicon's core operations. Indeed, one of the central allegations is that sotagliflozin was essential to the Company's survival. In addition, each annual report on Form 10-K and quarter report on form 10-Q filed by Lexicon during the Class Period, which was signed by the Individual Defendants and included certifications by the Individual Defendants as to the accuracy of the reports' contents, stated that sotagliflozin was one of Lexicon's "most advanced drug programs" and that the Company was "devoting most of [its] resources to the commercialization or development" of those programs, including sotagliflozin.
>
> Moreover, under the terms of the Sanofi Agreement, Lexicon had gra[n]ted Sanofi the entire rights to commercialize sotagliflozin for T1d and T2d outside of the United States. Thus Lexicon's royalties for sales of sotagliflozin outside of the United States paled in comparison to the royalty the Company was entitled to for sales of sotagliflozin inside the United States. Defendant Coats himself told analysts and investors on a March 1, 2016[,] conference call that royalties Sanofi would pay Lexicon would "range[] **from low double-digit**

> **percentages to 40% of net sales, specifically in the U.S.** and for type 1 diabetes." Accordingly, the Individual Defendants knew that for Lexicon to obtain the substantial royalties under the Sanofi Agreement, they could not rely on approval of sotagliflozin outside the United States; it was essential the FDA approve sotagliflozin.
>
> Finally, CW3, the former Head of Commercial Operations for Lexicon from August 2016 to March 2018, stated that Defendant Coats's compensation was directly tied to FDA approval of sotagliflozin. Defendant Coats thus was incentivized to fraudulently emphasize the modest benefits of sotagliflozin while concealing the risks of DKA. Defendants Wade and Lapuerta had compensation packages tied to FDA approval of sotagliflozin as well.[181]

The law in this circuit has long been well established that scienter in a particular case may not be based solely on motives universal to all corporate executives such as the desire to increase corporate earnings or to receive incentive compensation. See Abrams, 292 F.3d at 434. The Fifth Circuit affirmed the dismissal of similar claims based on incentive compensation in Tuchman v. DSC Communications Corp., 14 F.3d 1061 (5th Cir. 1994). There the Fifth Circuit stated that

> [i]ncentive compensation can hardly be the basis on which an allegation of fraud is predicated. One a practical level, were the opposite true, the executives of virtually every corporation in the United States would be subject to fraud allegations. It does not follow that because executives have components on their compensation keyed to performance, one can infer fraudulent intent.

Id. at 1068-69. Incentive compensation packages may be considered in conjunction with other scienter allegations, Barrie, 397 F.3d at

[181] FACAC, Docket Entry No. 27, pp. 77-78 ¶¶ 223-25.

264, but only in an extraordinary case is it probative. See Goldstein v. MCI WorldCom, 340 F.3d 238, 250 (5th Cir. 2003) (holding that compensation package was probative where MCI WorldCom CEO Bernard Ebbers had a unique pay package and stood to lose millions in compensation if WorldCom's stock price dropped significantly, and if his compensation suffered a materially adverse change, certain personal loans — which were secured by Ebbers' shares of WorldCom stock — would immediately become due). The FACAC contains no allegations of fact regarding any details of the Individual Defendants' compensation packages, much less details capable of establishing that this is an extraordinary case. Nor are there any allegations that any of the Individual Defendants engaged in insider trading or stood to benefit personally from any of the alleged misrepresentations. Plaintiffs offer no facts in support of their contention that any of the Individual Defendants were motivated to make the alleged misrepresentations with scienter other than the fact that, like the senior managers of every company, they had control over the Company.

In Indiana Electrical, 537 F.3d at 544, the Fifth Circuit recognized an exception to the rule that motives universal to all corporate executives are insufficient to raise a strong inference of scienter when a company is in need of completing a crucial transaction or particularly motivated to maintain or improve its credit rating. For example, in Ramirez v. Exxon Mobil Corp., 334

F.Supp.3d 832, 853 (N.D. Tex. 2018), the plaintiff alleged that at the time of a debt offering, the defendant company "was in dire financial need of an infusion of capital and that the Debt Offering was the 'largest single debt offering in [the company's] history.'" 334 F.Supp.3d at 853. Citing the exception recognized in Indiana Electrical, and observing that the plaintiff alleged facts capable of establishing that the defendant company lacked sufficient cash flow to pay the shareholders' dividends, and that both paying dividends and maintaining a AAA credit rating was extremely important to the company, the Ramirez court held that the plaintiff had alleged facts supporting a strong inference of scienter as to all of the defendants. Id.

Plaintiffs argue that the exception recognized in Indiana Electric applies in this case because one of their central allegations is that sotagliflozin was essential to the Company's survival. But the FACAC contains no allegations of fact comparable to those alleged in Indiana Electrical or Ramirez. The FACAC does not allege facts capable of establishing either that Lexicon had a crucial need for funds, or that Lexicon was particularly motivated to maintain or to improve its credit rating. And for reasons stated in the § II.B.1(b)(2)(i), above, the court has already concluded the FACAC contains no facts showing that sotagliflozin was essential to Lexicon's survival. Accordingly, the court concludes that plaintiffs' argument that defendants' desire for sotagliflozin to receive FDA approval do not support a strong inference of scienter as to any defendant.

(iii) Special Circumstances Do Not Apply

Citing Dorsey, 540 F.3d at 342, and asserting "allegations that a defendant made misstatements with scienter because of the defendant's senior position within the company are sufficient under 'special circumstances,'"[182] plaintiffs argue that facts capable of establishing three of the four special circumstances recognized in Dorsey are present in this case.[183] In Dorsey the Fifth Circuit applied special circumstances recognized in Nathenson, 267 F.3d at 400, to hold that defendants, by virtue of their positions as president and director of two very small businesses employing a total of eight workers in which the defendants ran all the day-to-day operations, could be imputed with knowledge of the company's failure to make secured loans. 540 F.3d at 342-43. The Fifth Circuit reiterated that such circumstances may include: (1) a small company in which corporate executives are more likely to be familiar with day-to-day operations; (2) transactions "critical to the company's continued vitality"; (3) omitted information readily apparent to the speaker; and (4) statements by the corporate officer that are internally inconsistent. Id. In Nathenson the company at issue was a single product company with only three dozen employees, and the statements alleged to be false and misleading were about the patent protection for that single product, the company's most crucial issue.

---

[182]Plaintiffs' Opposition, Docket Entry No. 35, p. 28.

[183]Id. at 29.

The Fifth Circuit and other courts have been reluctant, however, to apply the limited exception recognized in Nathenson. See Rosenzweig v. Azurix, 332 F.3d 854, 867-68 (5th Cir. 2003) (rejecting the plaintiffs' argument that "the failure of [defendant's] core business — water-privatization projects — supports the inference that defendants knew, or recklessly disregarded, [defendant's] prospects for success" and holding that the plaintiffs must identify exactly who supplied the information or when they knew the information"); Abrams, 292 F.3d at 432 ("A pleading of scienter may not rest on the inference that defendants must have been aware of the misstatement based on their positions within the company."). Instead, the Fifth Circuit has stated that only in the "rare case" will a strong inference of scienter be drawn from an officer's position in a company, and only when this factor combines with other, "special circumstances." Local 731 I.B of T. Excavators and Pavers Pension Trust Fund v. Diodes, Inc., 810 F.3d 951, 958-59 (5th Cir. 2016).

Plaintiffs argue that the

> FAC[AC] alleges three of four "special circumstances." First, sotagliflozin was essential to Lexicon because the Company had minuscule revenues, enormous debt and plummeting cash, and sotagliflozin was the only product that could make Lexicon profitable. ¶¶ 53-58. Second, the withheld or misrepresented information was readily apparent to Defendants because they oversaw the Phase 3 Trials, met with the FDA about the trials and communicated results to investors. See e.g., ¶¶ 52, 77, 96, 116, 140-41, 144, 150-51. Sotagliflozin was also one of Lexicon's "most advanced drug programs" to which the Company was "devoting most of [its] resources." ¶ 223.

> Finally, in November 2017, Coats told investors that Phase 3 Trials used a "[p]ragmatic study design reflecting [a] real-world setting." ¶ 147. The briefing document Lexicon submitted to the Committee, however, states that further study is needed in a "'real-world' setting." See Mot. at 20. This is an inconsistent statement because, after Coats promoted the trials' "real-world setting," Lexicon admitted that it needed to conduct trials in a real-world setting. See Dorsey, 540 F.3d at 342. Since three of four special circumstances are present, the Court may infer [d]efendants' scienter from their positions at Lexicon.[184]

The factual allegations in this case do not approximate those in Dorsey or Nathenson. In contrast to the small companies with a total of 8 and 36 employees, respectively, at issue in Dorsey and Nathenson, Lexicon was a growing company throughout the Class Period with 120 employees in February of 2016,[185] 168 employees in February of 2017,[186] 174 employees in February of 2018,[187] and 202 employees in February of 2019.[188] Moreover, Lexicon was not a single product company, and sotagliflozin was not the only Lexicon

---

[184] Id.

[185] 2015 Annual Report, Form 10-K, p. 12, Exhibit 1 to Defendants' Motion to Dismiss, Docket Entry No. 34-1, p. 15 ("As of February 29, 2016, we employed 120 persons. . .").

[186] 2016 Annual Report, Form 10-K, p. 13, Exhibit 3 to Defendants' Motion to Dismiss, Docket Entry No. 34-3, p. 17 ("As of February 28, 2017, we employed 168 persons. . .").

[187] 2017 Annual Report, Form 10-K, p. 16, Exhibit 4 to Defendants' Motion to Dismiss, Docket Entry No. 34-4, p. 19 ("As of February 26, 2018, we employed 174 persons. . .").

[188] 2018 Annual Report, Form 10-K, p. 17, Exhibit 1 to Plaintiffs' Opposition, Docket Entry No. 36-1, p. 25 ("As of February 28, 2019, we employed 202 persons . . .").

product capable of earning a profit. Each of the Lexicon Annual Reports cited in the FACAC identify other products in various stages of development, including XERMELO, which was approved by the FDA before the sotagliflozin phase 3 trials ended and was commercialized in 2017.[189] Although the FACAC alleges that Lexicon was dependent upon sotagliflozin's approval to survive, this allegation is conclusory, not supported by allegations of fact, and contradicted by disclosures in Lexicon's Annual Reports such as the statement that "[p]rior to the launch of XERMELO, we derived substantially all of our revenue from strategic collaborations and other research and development collaborations and technology licenses."[190]

The only "internally inconsistent" statement that plaintiffs identify is a statement made by Coats in an earnings call held on November 8, 2017, in which he said that the phase 3 trials used a "[p]ragmatic study design reflecting [a] real-world setting."[191]

---

[189]2017 Annual Report, Form 10-K, p. 2, Exhibit 4 to Defendants' Motion to Dismiss, Docket Entry No. 34-4, p. 5 ("We commercially launched XERMELO . . . following regulatory approval in the United States in February 2017 . . .").

[190]Id. at 24, Docket Entry No. 34-4, p. 27.

[191]FACAC, Docket Entry No. 27, p. 51 ¶ 147. See also November 8, 2017, Earnings Call Transcript, p. 8, Exhibit 21 to Defendants' Motion to Dismiss, Docket Entry No. 34-28, p. 9 ("Notably, in inTandem3, insulin was not optimized prior to randomization. That's a pragmatic design that we believe better reflects real-world experience. And we saw that drug-treated patients again demonstrated statistically significant reductions in A1c compared (continued...)

Plaintiffs argue that Coats' statement is inconsistent with a statement made in the briefing document Lexicon submitted to the Committee that further study is need in a real-world setting.[192] Defendants argue that "Lexicon's statement that it designed its study to reflect a "real world setting" is not inconsistent with a later statement that "further study is needed in a 'real-world setting.'"[193] When read in context these two statements are not contradictory because they address two different subjects. The statement Coats made during the November 8, 2017, earnings call addressed insulin optimization prior to randomization in the inTandem3 study. But the statement that plaintiffs cite from the brief that Sanofi submitted to the Advisory Committee addressed how to effectively manage the risk of DKA in a real-world setting.

In short, the FACAC does not allege special circumstances capable of supporting an assumption that because of their positions

---

[191](...continued) to placebo.").

[192]Plaintiffs' Opposition, Docket Entry No. 35, p. 29 (citing FACAC, Docket Entry No. 27, p. 51 ¶ 147, and Defendants' Motion to Dismiss, Docket Entry No. 33, p. 25. See Sanofi Briefing Document, Exhibit 2 to Defendants' Motion to Dismiss, p. 96, Docket Entry No. 34-2, p. 98) ("A Post Authorization Safety Study is planned to evaluate the risk of DKA in the post-marketing, 'real-world' setting. This retrospective cohort study will evaluate the risk of DKA in patients treated with sotagliflozin adjunct therapy in T1D as compared to patients treated with insulin alone, using existing large US healthcare databases.")).

[193]Defendants' Reply, Docket Entry No. 37, p. 10 & n. 9 (citing Plaintiffs' Opposition, Docket Entry No. 35, p. 29).

as officers of Lexicon the Individual Defendants' acted with scienter. The allegations in the FACAC do not raise an inference of intent or severe recklessness that is at least as compelling as the opposing inference one could draw from the facts alleged. Defendants invested significant resources in sotagliflozin's development, indicating genuine belief that the drug would receive FDA approval and be successfully marketed. Plaintiffs' factual allegations make it more plausible, or at least as plausible, to infer that when signing the SEC filings at issue the Individual Defendants honestly believed that the benefits of sotagliflozin outweighed its risks than to infer that they knowingly or recklessly disregarded the presence of glaring red flags in sotagliflozin's trial results. See Tellabs, 127 S. Ct. at 2510; Central Laborers, 497 F.3d at 555. The court therefore concludes that plaintiffs' factual allegations fail to raise a strong inference of scienter as to any of the Individual Defendants.

(3) Conclusions

The PSLRA requires plaintiffs to allege facts sufficient to raise a strong inference of scienter with respect to each defendant. R2 Investments, 401 F.3d at 643; Southland, 365 F.3d at 365; Indiana Electrical, 537 F.3d at 533. A complaint will survive a motion to dismiss "only if a reasonable person would deem the inference of scienter cogent and at least as compelling as any

opposing inference one could draw from the facts alleged." Tellabs, 127 S. Ct. at 2510. Plaintiffs argue that the FACAC's allegations regarding defendants' misrepresentations of the results of the phase 3 trials, entitlement to incentive compensation if sotagliflozin received FDA approval, need for sotagliflozin to be approved for the company to survive, together with the accounts of the three confidential witnesses, all support a strong inference of scienter.[194] The court concludes that taken together, all of the facts alleged in the FACAC fail to support a strong inference of scienter because plaintiffs have failed to allege facts regarding defendants' alleged misrepresentations, incentive compensation, dependence on sotagliflozin for survival, or confidential witness statements showing that any of the alleged misrepresentations were made with knowledge of their falsity or with reckless disregard for their truth or falsity.

(c) Plaintiffs Fail to Plead Loss Causation

Defendants argue that they are entitled to dismissal of the § 10(b) and Rule 10b-5 claims asserted against them because plaintiffs have failed to allege facts capable of establishing loss causation.[195] Defendants argue that

---

[194]Id. at 22-27.

[195]Defendants' Motion to Dismiss, Docket Entry No. 33, pp. 29-30. See also Defendants' Reply, Docket Entry No. 37, pp. 21-22.

> Plaintiffs' losses were admittedly caused by FDA's disappointing decision not to approve sotagliflozin as an adjunct to insulin for the treatment of type 1 diabetes and the announcement of Sanofi's purported termination of its collaboration agreement with Lexicon. Courts regularly dismiss securities fraud complaints, like the FAC[AC], that seek damages based on factors other than disclosure of misstated or omitted facts. Similarly, the FAC[AC]'s transparent attempt to collect damages caused by bad business results must be dismissed.[196]

Asserting that "the risk of DK was already disclosed and known to the market,"[197] defendants argue that the stock price declines following disclosures on January 17, March 22, and July 26, 2019, were caused not by fraud but by disappointment that the FDA would not approve sotagliflozin, a disclosed risk.[198]

Citing Dura Pharmaceuticals, Inc. v. Broudo, 125 S. Ct. 1627, 1634 (2005), plaintiffs argue that they "need only furnish the defendant[s] with 'some indication' of the causal connection between the misrepresentation and the loss to satisfy [their requirement to plead loss causation."[199] Citing Amedisys, 769 F.3d

---

[196]Defendants' Motion to Dismiss, Docket Entry No. 33, p. 30 & n. 46 (citing FACAC, Docket Entry No. 27, pp. 72-73 ¶ 212 (noting that Lexicon's stock price declined after disclosure of tie vote at the Advisory Committee); 73 ¶ 213 ("These declines were attributable to the disclosure of the Advisory Committee's decision not to recommend sotagliflozin for approval . . ."); 73-74 ¶ 215 (noting that Lexicon's stock price dropped after disclosure that the FDA would not approve sotagliflozin for T1d patients; and 77 ¶ 221 (noting that Lexicon's stock price dropped after Sanofi announced its intent to terminate the agreement with Lexicon)).

[197]Defendants' Reply, Docket Entry No. 37, p. 21.

[198]Id.

[199]Plaintiffs' Opposition, Docket Entry No. 35, p. 30.

at 325, for holding that "'the connection between [d]efendants' misleading statements and the alleged corrective disclosures . . . is a highly fact intensive inquiry that need not be reached at' the pleading stage,"[200] plaintiffs argue that defendants' arguments are not appropriate at this stage.

(1) Additional Law

The PSLRA, 15 U.S.C. § 78u-4(b)(4), requires plaintiffs to bear "the burden of proving that the act or omission of the defendant alleged to violate this chapter caused the loss for which the plaintiff seeks to recover damages." In Dura Pharmaceuticals, 125 S. Ct. at 1631, the Supreme Court held that the PSLRA requires plaintiffs to plead "loss causation, i.e., a causal connection between the material misrepresentation and the loss." See also Amgen, 133 S. Ct. at 1192, (confirming that loss causation continues to be an element of a private securities fraud action under § 10(b)). To plead loss causation plaintiffs

> must allege that when the "relevant truth" about the fraud began to leak out or otherwise make its way into the marketplace, it caused the price of the stock to depreciate and, thereby, proximately caused the plaintiff's economic harm.

Amedisys, 769 F.3d at 320 (citing Lormand, 565 F.3d at 255).

> Loss causation in fraud-on-the-market cases can be demonstrated circumstantially by "(1) identifying a 'corrective disclosure' (a release of information that reveals to the market the pertinent truth that was

---

[200] Id.

> previously concealed or obscured by the company's fraud); (2) showing that the stock price dropped soon after the corrective disclosure; and (3) eliminating other possible explanations for this price drop, so that the factfinder can infer that it is more probable than not that it was the corrective disclosure – as opposed to other possible depressive factors – that caused at least a 'substantial' amount of price drop".

Id. at 320-21 (quoting FindWhat Investor Group v. FindWhat.com, 658 F.3d 1282, 1311-12 (11th Cir. 2011), cert. denied, 133 S. Ct. 109 (2012)(emphasis added)). While the corrective disclosure need not be "complete" and "need not precisely mirror [an] earlier misrepresentation," the corrective disclosure "must reflect part of the 'relevant truth' – the truth obscured by the fraudulent statements." Alaska Electrical Pension Fund v. Flowserve Corp., 572 F.3d 221, 230 (5th Cir. 2009) (per curiam). "Plaintiffs are required to allege the truth that emerged was 'related to' or 'relevant to' the defendants' fraud and earlier misstatements." Amedisys, 769 F.3d at 321. "The test for relevant truth simply means that the truth disclosed must make the existence of the actionable fraud more probable than it would be without that alleged fact, taken as true." Id. (citing Lormand, 565 F.3d at 256 n. 20). See also Spitzberg, 758 F.3d at 688 (confirming that "the applicable standard in this circuit under Lormand, 565 F.3d at 256 n. 20, is that a corrective disclosure must 'make the existence of the actionable fraud more probable than it would be without that alleged fact (taken as true).'").

> A corrective disclosure can come from any source and "can be gradually perceived in the marketplace through a series of partial disclosures." . . . When a complaint alleges a series of partial disclosures, the court may analyze each in isolation but should also "consider them collectively in determining whether a corrective disclosure has occurred."

Schott v. Nobilis Health Corp., 211 F.Supp.3d 936, 950-51 (S.D. Tex. 2016) (quoting Amedisys, 769 F.3d at 322). See also Lormand, 565 F.3d at 261 ("[L]oss causation may be pleaded on the theory that the truth gradually emerged through a series of partial disclosures and that the entire series of partial disclosures caused the stock price deflation.").

(2) Analysis

Plaintiffs allege that the Advisory

> Committee Meeting was the first time [(i)] that the market learned of the full extent of the increase in DKA in patients taking sotagliflozin over patients taking placebo; (ii) that the FDA had specifically warned [d]efendants that the composite endpoint was not reliable and hid the risk of DKA; (iii) that the benefits of sotagliflozin were only modest; (iv) that the Time-in-Range and Glycemic Variability measures touted by Lexicon had not been validated for use in regulatory decision making for antidiabetic drugs, and (v) that Lexicon did not have a meaningful risk management plan for DKA, which was essential to the successful approval of sotagliflozin.[201]

Plaintiffs allege that on news that the Advisory Committee had deadlocked on the question of whether "the benefits of sotagliflozin outweighed the risks to support approval," Lexicon's

[201]FACAC, Docket Entry No. 27, p. 72 ¶ 211.

share price fell from $7.70 to $5.96 per share, and that as the market recognized the extent of defendants' misrepresentations and omissions the share price fell again "hitting bottom at $4.46 on January 25, 2019, a decline of over 42% [from] its closing price on January 16, 2019."[202] Plaintiffs allege that

> [t]hese declines were attributable to the disclosure of the Advisory Committee's decision not to recommend sotagliflozin for approval, which revealed that [d]efendants had been making false and misleading statements and/or omissions concerning the risk to patients of DKA, the drug's effectiveness, the FDA's concerns regarding the 'composite endpoint' . . . and [d]efendants' touting of [] sotagliflozin's performance with regards to measures that had not been validated by the FDA for use in regulatory decision making.[203]

But missing from the FACAC are allegations that the alleged misrepresentations caused inflation of the price of Lexicon's common stock. Simply alleging that plaintiffs purchased Lexicon's common stock at inflated prices and that the stock price fell after negative news of the company's operations came out is not sufficient to plead loss causation. Lormand, 565 F.3d at 256 (citing Dura Pharmaceuticals, 125 S. Ct. at 1633-34). Plaintiffs must also make a plausible showing of loss causation, i.e., that when "the 'relevant truth' about the fraud began to leak out or otherwise make its way into the marketplace it caused the price of the stock to depreciate and thereby proximately cause the

---

[202] Id. at 72-73 ¶ 212.

[203] Id. at 73 ¶ 213.

plaintiff's economic loss." Id. at 255. Plaintiffs must allege that the stock price declined in response to a "corrective disclosure," i.e., "the truth obscured by the fraudulent statements." Alaska Electrical Pension Fund, 572 F.3d at 230. Plaintiffs fail to identify any corrective disclosures made during the Advisory Committee Meeting. As discussed in the previous sections of this Memorandum Opinion and Order, when the Advisory Committee met on January 17, 2019, the proponents of the NDA had their views, the FDA staff had its views, and the Advisory Committee voted eight-to-eight on the question of whether sotagliflozin's benefits outweighed its risks to support FDA approval. Neither the FDA's views, nor the comments or vote of the Committee Members mean that the information issued publicly over the course of the phase 3 trials and the almost three and a half year Class Period was false or misleading, or that the discussions at the Advisory Committee Meeting constitute corrective disclosures. Accordingly, for essentially the same reasons that the court has already concluded that plaintiffs have failed to allege facts capable of establishing that any of the alleged misrepresentations are actionable, or that any of the alleged misrepresentations were made with scienter, the court concludes that plaintiffs have also failed to allege facts capable of establishing loss causation with respect to disclosures made during the Advisory Committee Meeting. See Markman v. Whole Foods Market,

Inc., No. 1:15-CV-681-LY, 2016 WL 10567194, *12 (W.D. Tex. Aug. 19, 2016) ("[I]n the absence of a false representation, there can be no revelation of falsity to the market.") (citation omitted).

Plaintiffs allege that Lexicon's stock price fell again on March 22, 2019, following disclosure that the FDA had issued a "Complete Response Letter" stating that the FDA would not approve sotagliflozin,[204] and again on July 29, 2019, following Sanofi's announcement that it was terminating the Sanofi Agreement with Lexicon.[205] Plaintiffs allege that the losses occurring in March and July 2019 represented

> a materialization of the risk stemming from [d]efendants' false and misleading statements and/or omissions concerning the risk to patients of DKA, the drug's effectiveness, the FDA's concerns regarding the 'composite endpoint' in the Phase 3 Trials and [d]efendants' touting of [] sotagliflozin's performance with regards to measures that had not been validated by the FDA for use in regulatory decision making, which had already led to the Advisory Committee's deadlocked vote at the Committee Meeting and the FDA's decision not to approve sotagliflozin as a T1d treatment.[206]

Because the FACAC does not allege facts capable of establishing that the disclosures made in March and July of 2019 corrected any misrepresentations made earlier, these disclosures do not qualify as corrective, and plaintiffs has failed to allege loss causation with respect to them. See id.

---

[204] Id. at 73 ¶ 215.

[205] Id. at 77 ¶ 221.

[206] Id. at 76-77 ¶ 220.

2. Claims for Violation of § 20(a) Control Person Liability

Plaintiffs allege that the Individual Defendants, Coats, Lapuerta, and Ward are liable as "control persons" of Lexicon under § 20(a) of the Exchange Act.[207] Section 20(a) imposes joint and several liability for securities fraud on "[e]very person who, directly or indirectly, controls any person liable under any provision of this chapter or of any rule or regulation thereunder." 15 U.S.C. § 78t(a). "Control person liability is secondary only and cannot exist in the absence of a primary violation." Southland, 365 F.3d at 383. Defendants argue that the control person claims asserted in the FACAC are subject to dismissal because the primary claims under § 10(b) are subject to dismissal. Because the court has concluded that the § 10(b) and Rule 10b-5 claims asserted in the FACAC are subject to dismissal for failure to allege an actionable misrepresentation, failure to plead facts supporting a strong inference of scienter, and failure to plead loss causation, the § 20(b) claim that plaintiffs have asserted against the Individual Defendants, Coats, Lapuerta, and Ward are also subject to dismissal. Id. at 383-84. See also Alaska Electricians Pension Fund, 915 F.3d at 986 ("Because Plaintiffs have not established a primary violation, their Section 20(a) claims fail.").

---

[207]Id. at 40-42 ¶¶ 134-41.

III. **Plaintiffs' Request to Amend**

At the end of Plaintiff's Memorandum of Law in Opposition to Defendants' Motion to Dismiss, plaintiffs assert that "[i]f the Court grants any portion of the Motion, Plaintiffs respectfully request 30 days to move to amend pursuant to Fed. R. Civ. Proc. 15(a)(2)."[208] Federal Rule of Civil Procedure 15(a)(2) states that "[t]he court should freely give leave [to amend] when justice so requires." "Although Rule 15[a] 'evinces a bias in favor of granting leave to amend,' it is not automatic." Matter of Southmark Corp., 88 F.3d 311, 314 (5th Cir. 1996), cert denied, 117 S. Ct. 686 (1997) (quoting Dussouy v. Gulf Coast Investment Corp., 660 F.2d 594, 597 (5th Cir. 1981)). "A decision to grant leave is within the discretion of the trial court." Id. (citing State of Louisiana v. Litton Mortgage Co., 50 F.3d 1298, 1302-1303 (5th Cir. 1995) (per curiam)). In exercising its discretion, a court may consider various criteria including, inter alia, the failure to cure deficiencies by amendments previously allowed and futility of the proposed amendment. Id. at 314-15 (citing Foman v. Davis, 83 S. Ct. 227, 230 (1962)). Because plaintiffs have already filed an amended complaint that is 88 pages long, and have argued strenuously that the FACAC states claims for which relief may be granted, and because plaintiffs have failed either to submit a proposed second amended complaint or described any additional facts

---

[208]Plaintiff's Opposition, Docket Entry No. 35, p. 31.

that could be alleged in a second amended complaint that could not have been alleged in the FACAC, the court is persuaded that plaintiffs have pleaded their best case, and that any additional attempt to amend would be futile. Accordingly, plaintiff's request for leave to amend will be denied. See Rosenzweig, 332 F.3d at 865 (affirming district court's denial of plaintiff's motion to file a second amended complaint).

IV. Conclusions and Order

For the reasons stated in § II, above, the court concludes that plaintiffs have failed to state claims for violations of §§ 10(b) and 20(a) of the Securities Exchange Act of 1934, 15 U.S.C. §§ 78j(b), 78t(a) and Rule 10b-5 promulgated thereunder, 17 C.F.R. § 240.10b-5. Accordingly, Defendants' Motion to Dismiss Amended Complaint, Docket Entry No. 33, is **GRANTED**.

For the reasons stated in § III, above, the court concludes that plaintiffs should not be allowed an additional opportunity to amend. Accordingly, plaintiffs' Request to Amend stated at the end of Plaintiffs' Opposition to Defendants' Motion to Dismiss, Docket Entry No. 35, is **DENIED**.

SIGNED at Houston, Texas, on this 14th day of August, 2020.

SIM LAKE
SENIOR UNITED STATES DISTRICT JUDGE